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Preempting Food Safety: An Examination of USDA Rulemaking and Its E.coli O157:H7 Policy in Light of Estate of Kriefall ex rel. Kriefall v. Excel Corporation

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PREEMPTING FOOD SAFETY: AN EXAMINATION OF USDA RULEMAKING AND ITS *E. COLI* O157:H7 POLICY IN LIGHT OF *ESTATE OF KRIEFALL EX REL. KRIEFALL v. EXCEL CORPORATION*[1]

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I. INTRODUCTION

> From early times, people have relied on the skill and care of others to catch, grow, gather, preserve, prepare, and provide much of the food and drink indispensable to survival. Whether paid for with a beaver pelt, a copper coin, or a modern dollar, food has always been the single most important product bought and sold by human beings . . . . Because pure food is necessary to survival, rendering most persons extraordinarily dependent for their health, safety, and very lives on the care and skill of food providers, the rules that govern liability for selling defective food and drink have long stood apart from those concerning other types of products.[2]

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1. The correct case-name citation, according to THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 18th ed. 2005), Rule 10.2.1(a), would be Estate of Kriefall *ex rel.* Kriefall v. Sizzler USA Franchise, Inc. Because Sizzler USA was aligned with the interests of the plaintiffs on appeal, and for sake of emphasis, the case will be cited throughout as Estate of Kriefall ex rel. Kriefall v. Excel.

2. David G. Owen, *Manufacturing Defects*, 53 S.C. L. REV. 851, 884 (2002). Summarizing the law as it relates to manufacturing defects, Professor Owen reminds us that the origin of the rules of product liability are in defective food and drink cases, concluding that: "Responsibility for manufacturing defects is the most fundamental obligation of product manufacturers. The law governing production

Before the lawsuit levy broke and its alleged fraud on the public revealed, the cigarette industry must have been the envy of consumer product manufacturers everywhere. The cigarette industry offered a product that caused near-incalculable harm to generations of its users, but for decades cigarette manufacturers enjoyed immunity from all forms of product liability claims.[3] Examining the strategy of the cigarette industry, the meat industry appears intent on using the authority of the United States Department of Agriculture (USDA) to promulgate rules pursuant to the Federal Meat Inspection Act (FMIA)[4] and its stamp of inspection[5] to preempt state tort or product liability claims, and thus gain immunity from liability for the manufacture or sale of many kinds of unsafe meat.[6]

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errors is now quite settled, and it remains the first pillar of modern products liability law." *Id.* at 905.

3. M. Siegel et al., *Preemption in Tobacco Control. Review of an Emerging Public Health Problem*, 278 J. AM. MED. ASS'N, Sept. 10, 1997, (No. 10) at 860-63 (concluding that preemption of state and local tobacco regulations is an important strategy that undermines the public health and arguing that preventing the enactment of new preemption laws and repealing existing ones should become a public health priority). *See also* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 531 (1992) (applying federal preemption doctrine to a product liability case and holding that certain state law failure-to-warn claims arising out of the sale of cigarettes were preempted by state law).

4. 21 U.S.C. §§ 601- 695 (2000).

5. 21 U.S.C. § 606 (2000) (declaring that "inspectors shall mark, stamp, tag, or label as 'Inspected and passed' all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all such products found adulterated").

6. Here and throughout this article, the term "unsafe meat" will be used to describe meat that causes injury to a person as a proximate result of it being contaminated with a pathogen. It should also be noted that the term "contaminated" is to be distinguished from "adulterated." As typically used, the term "contaminated" is legally neutral; it describes a product that has a pathogen or foreign substance in or on it. In contrast, the term "adulterated" is used when the contamination involves an "adulterant," as defined by statute. *See, e.g.*, 21 U.S.C. § 601(m)(1) (defining "adulterated" as "bear[ing] or contain[ing] any poisonous or deleterious substance which may render it injurious to health"). *Cf.* Supreme Beef Processors, Inc. v. USDA, 275 F.3d 432, 438-39 (5th Cir. 2001) (enjoining FSIS's use of *Salmonella* performance standards, noting that since 1974, *Salmonella* has not been deemed an adulterant per se when present in or on meat and poultry); *but see* Blake B. Johnson, *The Supreme Beef Case: An Opportunity to Rethink Federal Food Safety Regulation*, 16 LOY. CONSUMER L. REV. 159, 174 (2004) (concluding, without noting the irony, that "it would appear that meat packing associations and their contingent

A glimpse of this strategy can be found in the approach taken by the Excel Corporation in a case arising from an outbreak of *E. coli* O157:H7 infections linked by a health department investigation of two Sizzler restaurants in the area of Milwaukee, Wisconsin.[7] In that case, Excel, one of several defendants in the case, successfully moved for summary judgment dismissal of all state tort claims against it on the grounds that the claims were preempted by FMIA.[8] The grant of summary judgment was reversed by a decision of the Wisconsin Court of Appeals in *Estate of Kriefall ex rel. Kriefall v. Excel.*[9] Excel petitioned first the Wisconsin Supreme Court and then the United States Supreme Court for appeal, but both petitions were denied.[10] With the exhaustion of appeals, the decision of the Court of Appeals became the law and provided persuasive authority against any future attempt to use FMIA to preempt state tort law.

Notably, at all stages of the litigation—from summary judgment to the petition for writ of certiorari to the United States Supreme Court—Excel was joined and supported by briefs filed by amici curiae representing the interests of the meat and poultry industry.[11]

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interest groups are willing to fight against regulation designed to protect the public").

7. Wisconsin Division of Public Health, Final Report, *Investigation of an Outbreak of* E. coli *O157:H7 Infection at the Layton Avenue Sizzler Restaurant, Milwaukee, WI; July-August, 2000*, (Oct. 6, 2000) (on file with author) [hereinafter Final Report].

8. Decision on Excel Corporations [*sic*] Motion for Summary Judgment, In re Consolidated E. coli O157:H7 Cases, No. 00-CV-006503 (Milwaukee Cir. Ct. May 15, 2002) (granting summary judgment dismissing all claims).

9. 665 N.W.2d 417, 437 (Wis. Ct. App. 2003) (holding that language in FMIA, 21 U.S.C. § 678, that prohibited a state from imposing requirements with respect to the premises, facilities, and operations of a federally-inspected meat processing facility did not preempt state tort claims based on the sale of contaminated meat). Excel had sought to have the decision on summary judgment made in a federal forum, removing the cases under the Federal Officers Removal Statute, 28 U.S.C. § 1442(a)(1), but this procedural stratagem failed when the U.S. District Court granted the plaintiffs' motion to remand. *See infra* notes 135-37 and accompanying text. It is commonly thought that federal courts are more receptive to preemption arguments, thus Excel's desire for a federal forum. *See* David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 412-14 (2003) ("In general, federal courts are more willing than state courts to find preemption.").

10. Estate of Kriefall ex rel. Kriefall v. Sizzler USA Franchise, Inc., 671 N.W.2d 849 (Wis. 2003) (denying petition for review); Excel Corp. v. Estate of Kriefall, 541 U.S. 956 (2004) (denying Excel's petition for writ of certiorari).

11. See, e.g., Memorandum of Amici Curiae In Support of Excel's Motion for Summary Judgment, *In re Consolidated E. coli O157:H7 Cases*, No. 00-CV-006503 (Milwaukee Cir. Ct. May 15, 2002) [hereinafter Amici Memorandum]. The amici

In the brief filed in support of Excel's motion for summary judgment, the amici described their "substantial interest" in the litigation as follows:

> Over ninety-five (95) percent of all beef, chicken, turkey, pork, lamb and veal products sold in the United States are produced by the members of the *Amici* associations. An adverse decision here would allow states (and individual courts) to adopt differing adulteration standards. This would create chaos for the more than 6,000 inspected establishments and would disrupt the Nation's food supply.[12]

Given the unanimity of support provided by the Meat Industry for Excel's legal strategy, and its position on FMIA preemption of state tort law, Excel's efforts may be interpreted as representing the views of the Meat Industry. In sum, Excel's position was the Meat Industry's position; they were in this preemption fight together.

This article will use the *Kriefall* decision to examine USDA rulemaking and its still-evolving *E. coli* O157:H7 policy. Part II of the article will briefly describe the development and implementation of the USDA *E. coli* O157:H7 policy as a reaction to an enormous and widely-publicized outbreak of *E. coli* infections that occurred in 1993—the so-called Jack in the Box outbreak.[13] Following the outbreak, *E. coli* O157:H7 was declared by USDA to be an adulterant per se according to FMIA.[14] It was also at this time that the first steps were taken by USDA to move from a "command and control" inspection model to the current "science-based" Hazard Analysis Critical Control Point (HACCP)[15] model.[16] These actions

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were the American Meat Institute (AMI), the National Chicken Council, the National Meat Association, the National Turkey Federation, the North American Meat Processors Association, and the Southwest Meat Association. *Id.* Excel is listed as a member of AMI on its website. *See* AMI, *at* http://www.meatami.com/Content/NavigationMenu/Buy_Sell/AMIMemberCompanyLinks/GeneralMemC-E.htm (last visited Jan. 28, 2006). *See also Kriefall*, 665 N.W.2d 417, 420-21 n.1 (Wis. Ct. App. 2003) (acknowledging that a "joint *amici curiam* brief has been filed").

12. Amici Memorandum, *supra* note 11, at 2. Except when reference is being made to Excel alone, hereinafter "Meat Industry" shall be used to collectively refer to the industry interests represented by Excel and the amici trade associations.

13. *See infra* Section II.B.1.

14. *See* Jean M. Rawson, *IB10037: Meat and Poultry Inspection Issues*, July 22, 1999, *available at* http://ncseonline.org/NLE/CRSreports/Agriculture/ag-30.cfm.

15. *See id.* This is an acronym (generally pronounced as "hass-sup") standing for Hazard Analysis Critical Control Plan. For a succinct overview of the development of the HACCP paradigm and its adoption by the Food and Drug Administration

represented a fundamental shift in how USDA operated, and demonstrated a renewed ability to put public interests ahead of traditional deference to Meat Industry concerns. This deference—best described as "agency capture"[17]—had put public safety at risk and eroded the legitimacy of USDA food safety actions, especially its continued reliance on an organoleptic inspection system that was incapable of detecting dangerous microbial pathogens.[18]

Section III of the article will describe and discuss the 2000 Sizzler *E. coli* outbreak and the resulting litigation. Focus will be placed upon Excel's effort to use FMIA as a shield against liability under state law. While Excel did not ultimately prevail, the history of the litigation reveals much about what the Meat Industry appears to believe is at stake. Notably, while enjoying considerable freedom under the current HACCP-based regulatory scheme, Meat Industry rhetoric continued to describe—or more accurately, exaggerate—the extent of government control as if each inspected facility was under

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(FDA) and USDA as the primary conceptual framework for food safety reform efforts, see Michael R. Taylor, *Preparing America's Safety System for the Twenty-First Century—Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?* 52 FOOD & DRUG L.J. 13, 20-23 (1997) (arguing that the federal government's adoption of HACCP was only a first step, and that much remains to be done to ensure the food system's future success). The basic reference for HACCP is not FDA or USDA, but the National Advisory Committee on Microbiological Criteria for Food (NACMCF). *See* NACMCF, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, 61 J. FOOD PROTECTION (No. 9) 1246-59 (1998). "Under the current structure, HACCP is a different system at FDA and USDA." Caroline Smith DeWaal, *Food Safety Inspections: A Call for Rational Reorganization*, 54 FOOD & DRUG. L.J. 453, 456 (1999) (criticizing the FDA's HACCP program as "in effect, an industry honor system," and calling for greater standardization and coordination among the agencies). Among the USDA inspectors, the acronym HACCP has achieved a telling alternate meaning—"Have a Cup of Coffee and Pray." Kerri E. Machado, Comment, *"Unfit for Human Consumption": Why American Beef is Making Us Sick*, 13 ALB. L.J. SCI. & TECH. 801, 817 (2003).

16. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806, 38,806-38,989 (July 25, 1996), *codified at* 9 C.F.R. pts. 304, 308, 310, 320, 327, 381, 416, & 417 [hereinafter HACCP Final Rule].

17. Machado, *supra* note 15, at 825 ("Agency capture means that the private interests of the meatpackers have taken control over and influence regulatory agencies.").

18. *Id.* at 816 (stating that "with continuing developments in science and technology, the mere visual, tactile, and olfactory inspection of animals became clearly outdated").

government occupation. This exaggeration forms the basis of the Meat Industry's preemption argument.

Section IV of the article argues against regulatory preemption of state tort claims, like that sought in *Kriefall*. The article will suggest that in the absence of civil lawsuits that force meat processors to bear the cost of the injuries caused by their unsafe and mismanufactured products, regulatory compliance will be the primary and less effective incentive for food safety innovation and investment. USDA should therefore make clear that unless and until Congress expressly decides otherwise, USDA does not intend for its regulations to preempt state law tort claims premised on an alleged defect in a meat product.[19] Only a policy against preemption will create sufficient additional incentives for the Meat Industry to continue to invest in further food safety innovations beyond that which is required by USDA.

The article will conclude by contending that the USDA's *E. coli* O157:H7 policy should be one of zero-tolerance on all meat and poultry products. By failing to take into account common food-handling practices, and the substantial risk of cross-contamination between raw meat and other food items intended for immediate consumption, USDA endangers the public by allowing the Meat Industry to distribute intact meat contaminated with *E. coli* O157:H7. Having declared *E. coli* O157:H7 as an adulterant per se based upon "the low infectious dose [it] associated with foodborne disease outbreaks and the very severe consequences of an *E. coli*

19. A detailed discussion of how courts should decide the issue of preemption is beyond the scope of this article. It should be emphasized, however, that the continuing chaos of preemption jurisprudence is an important additional reason for an agency to be cognizant that its own failure to speak clearly on the issue of preemption will only add to the existing chaos. *See* Owen, *supra* note 9, at 412-13 and nn.3-11 (2003) (concluding that the doctrine of federal preemption "continues to wallow in a state of utter chaos" and noting that other commentators agree). Also beyond the scope of this Article is the question of whether, how, or when agency-action should result in the preemption of state tort claims. For an excellent discussion of this question, see David A. Herrman, *To Delegate or Not to Delegate—That is Preemption: The Lack of Political Accountability in Administrative Preemption Defies Federalism Constraints on Government Power*, 28 PAC. L.J. 1157, 1190-97 (1997) (pointing out that the main reason administrative preemption is able to avoid federalism restraints is because Congress blurs its own responsibilities for controversial lawmaking by delegating this responsibility away).

O157:H7 infection,"[20] the Agency should not accede to the Meat Industry's efforts to create a trace-tolerance level for the pathogen. In order to meet the goal of FMIA to protect the consuming public, a zero-tolerance policy for *E. coli* O157:H7 should be mandated.

II. THE USDA *E. COLI* O157:H7 POLICY: FROM REACTION TO RETRENCHMENT

The development and implementation of the Agency's *E. coli* O157:H7 policy continues to evolve, driven by the demands of the public for safe meat, but ultimately shaped by meat industry's influence and resistance to regulation and pathogen-testing.[21] The starting point for any discussion of this policy must begin with the unique dangers posed to the public—especially children—by this pathogen.

A. E. coli *O157:H7: A Decidedly Deadly Pathogen*

E. coli O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*.[22] Most strains of *E. coli* are harmless and live in the intestines of healthy humans and animals.[23] The *E. coli* bacterium is among the most extensively studied microorganisms.[24] The combination of letters and numbers in the name of the *E. coli* O157:H7 refers to the specific markers found on its surface and

20. Beef Products Contaminated with *Escherichia coli* O157:H7, 64 Fed. Reg. 2803 (Jan. 19, 1999) [hereinafter Non-Intact Meat Policy Statement].

21. *See generally* MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM 62-85 (2003) (describing the twenty years of consistent and often successful efforts to block regulations that might adversely affect the meat industry's commercial interests, the denial of responsibility for outbreaks of foodborne illness, and the invocation of science as a means to prevent unwanted oversight).

22. *E. coli* bacteria were discovered in the human colon in 1885 by German bacteriologist Theodor Escherich. Peter Feng, Stephen D. Weagant, & Michael A. Grant, *Enumeration of* Escherichia coli *and the Coliform Bacteria*, *in* BACTERIOLOGICAL ANALYTICAL MANUAL (8th ed. 2002), *available at* http://www.cfsan.fda.gov/~ebam/bam-4.html. Dr. Escherich also showed that certain strains of the bacteria were responsible for infant diarrhea and gastroenteritis, an important public health discovery. *Id.* Although the bacteria were initially called Bacterium *coli*, the name was later changed to *Escherichia coli* to honor its discoverer. *Id.*

23. NESTLE, *supra* note 21, at 40-41.

24. JAMES M. JAY, MODERN FOOD MICROBIOLOGY 21 (Aspen Publishers, Inc. 6th ed. 2000) ("This is clearly the most widely studied genus of all bacteria.").

distinguishes it from other types of *E. coli*.[25] The testing performed to distinguish *E. coli* O157:H7 from its other *E. coli* counterparts is referred to as serotyping.[26] Pulsed-field gel electrophoresis (PFGE),[27] sometimes also referred to as genetic fingerprinting, is used to compare *E. coli* O157:H7 isolates to determine whether the strains are distinguishable.[28]

E. coli O157:H7 was first recognized as a pathogen in 1982 during an investigation into an outbreak of hemorrhagic colitis[29] associated with consumption of hamburgers from a fast food restaurant.[30] Retrospective examination of more than 3,000 *E. coli* cultures obtained between 1973 and 1982 found only one isolation with serotype O157:H7, and this culture pertained to a 1975 case.[31]

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25. Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC), Escherichia coli *O157:H7*, *available at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm.

26. Beth B. Bell et al., *A Multistate Outbreak of* Escherichia coli *O157:H7-Associated Bloody Diarrhea and Hemolytic Uremic Syndrome from Hamburgers: The Washington Experience*, 272 J. AM. MED. ASS'N (No. 17) 1349, 1350 (Nov. 2, 1994) (describing the multiple step testing process used to confirm, during a 1993 outbreak, that the implicated bacteria were *E. coli* O157:H7).

27. *See* JAY, *supra* note 24, at 220-21 (describing in brief the PFGE testing process).

28. *See id.* Through PFGE testing, isolates obtained from the stool cultures of probable outbreak cases can be compared to the genetic fingerprint of the outbreak strain, confirming that the person was in fact part of the outbreak. Bell et al., *supra* note 26, at 1351-52. Because PFGE testing soon proved to be such a powerful outbreak investigation tool, PulseNet, a national database of PFGE test results was created. Bala Swaminathan et al., *PulseNet: The Molecular Subtyping Network for Foodborne Bacterial Disease Surveillance, United States*, 7 EMERGING INFECT. DIS. (No. 3) 382, 382-89 (May-June 2001) (recounting the history of PulseNet and its effectiveness in outbreak investigation).

29. "[A] type of gastroenteritis in which certain strains of the bacterium *Escherichia coli* (*E. coli*) infect the large intestine and produce a toxin that causes bloody diarrhea and other serious complications." MERCK MANUAL ONLINE MEDICAL LIBRARY, *Hemorrhagic Colitis*, *at* http://www.merck.com/mmhe/sec09/ch122/ch122b.html (last visited Jan. 9, 2006).

30. Lee W. Riley et al., *Hemorrhagic Colitis Associated with a Rare Escherichia coli Serotype*, 308 NEW. ENG. J. MED. 681, 684-85 (1983) (describing investigation of two outbreaks affecting at least forty-seven people in Oregon and Michigan both linked to apparently undercooked ground beef); Chinyu Su & Lawrence J. Brandt, Escherichia coli *O157:H7 Infection in Humans*, 123 ANNALS INTERN. MED. (Issue 9), 698, 698-707 (1995) (describing the epidemiology of the bacteria, including an account of its initial discovery).

31. Riley et al., *supra* note 30 at 684-85. *See also* Patricia M. Griffin & Robert V. Tauxe, *The Epidemiology of Infections Caused by* Escherichia coli *O157:H7, Other Entero-*

In the ten years that followed, approximately thirty outbreaks were recorded in the United States.[32] However, this statistic is somewhat misleading because an *E. coli* O157:H7 infection did not become a reportable disease in any state until 1987 when Washington became the first state to mandate its reporting.[33] As a result, only the most geographically concentrated outbreak of the deadly pathogen would have garnered enough notice to prompt further investigation.[34]

The virulence of *E. coli* O157:H7 is a result of its ability to produce Shiga-like toxins.[35] It was theorized that generic *E. coli* acquired this deadly ability to produce Shiga-like toxins through horizontal transfer of virulence genes from the *Shigella* bacteria.[36] Genome sequencing of *E. coli* O157:H7 has since confirmed that gene transfer did in fact occur, and the evolution of even more virulent forms of bacteria is likely to continue to occur.[37] CDC has

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hemorrhagic E. coli, *and the Associated Hemolytic Uremic Syndrome*, 13 EPIDEMIOLOGIC REVS. 60, 73 (1991).

32. Peter Feng, Escherichia coli *Serotype O157:H7: Novel Vehicles of Infection and Emergence of Phenotypic Variants*, 1 EMERGING INFECT. DIS. (No. 2), 47, 47 (Apr.-Jun. 1995) (noting that, despite these earlier outbreaks, the bacteria did not receive any considerable attention until ten years later when an outbreak occurred in 1993 that involved four deaths and over 700 infected people). *See* discussion *infra* at Section II.B.

33. William E. Keene et al., *A Swimming-Associated Outbreak of Hemorrhagic Colitis Caused by* Escherichia coli *O157:H7 and* Shigella Sonnei, 331 NEW ENG. J. MED. 579 (Sept. 1, 1994). *See also* Stephen M. Ostroff, John M. Kobayashi & Jay H. Lewis, *Infections with* Escherichia coli *O157:H7 in Washington State: The First Year of Statewide Disease Surveillance*, 262 J. AM. MED. ASS'N (No. 3) 355, 355 (July. 21, 1989) ("It was anticipated that the reporting requirement would stimulate practitioners and laboratories to screen for the organism.").

34. *See* Keene et al., *supra* note 33, at 583 ("With cases scattered over four counties, the outbreak would probably have gone unnoticed had the cases not been routinely reported to public health agencies and investigated by them."). With improved surveillance, mandatory reporting in forty-eight states, and the broad recognition by public health officials that *E. coli* O157:H7 was an important and threatening pathogen, there was a total of 350 reported outbreaks from 1982-2002. Josefa M. Rangel et al., *Epidemiology of* Escherichia coli *O157:H7 Outbreaks, United States, 1982-2002*, 11 EMERGING INFECT. DIS. (No. 4) 603, 604 (Apr. 2005).

35. *See* Griffin & Tauxe, *supra* note 31, at 61-62 (noting that the nomenclature came about because of the resemblance to toxins produced by *Shigella dysenteriae*).

36. *See id.* at 62 (using the more technical term "phage-mediated transfer").

37. Nicole T. Perna et al., *Genome Sequence of Enterohaemorrhagic* Escherichia coli *O157:H7*, 409 NATURE 529-30 (Jan. 25, 2001) (finding that *E. coli* O157:H7 has 1,387 genes not found in non-pathogenic *E. coli*). *See also* Robert V. Tauxe, *Emerging Foodborne Diseases: An Evolving Public Health Challenge*, 3 EMERGING INFECT. DIS. 425 (Oct.-Dec. 1997) (arguing that the epidemiology of foodborne disease will

emphasized the prospect of emerging pathogens as a significant public health threat for some time.[38]

Foods of a bovine origin are the most common cause of both outbreaks and sporadic cases of *E. coli* O157:H7 infections.[39] Surveys performed on feed lots have demonstrated that cattle may become infected with *E. coli* O157:H7 through close contact and in muddy conditions.[40] The prevalence of *E. coli* O157:H7 among cattle in feed lots can reach magnitudes of 63-100% of the lot, especially during the summer.[41] The prevalence of *E. coli* O157:H7 in the summer is a significant public safety risk.[42]

According to a recent study, an "estimated 73,480 illnesses due to *E. coli* O157 infection occur each year in the United States, leading to an estimated 2,168 hospitalizations and sixty-one deaths."[43] The hemorrhagic colitis caused by *E. coli* O157:H7 is characterized by severe abdominal cramps, bloody stool, but sometimes little or no fever.[44] The typical incubation period, the time from exposure to the onset of symptoms, is reported as three to eight days.[45] Infection can occur in people of any age but is most

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continue to change, requiring increased collaboration of regulatory agencies and meat industry, and the strengthening of surveillance and research efforts).

38. Tauxe, *supra* note 37, at 427 ("After [fifteen] years of research, we know a great deal about infections with *E. coli* O157:H7, but we still do not know how best to treat the infection, nor how the cattle (the principal source of infection for humans) themselves become infected."). FSIS failed to respond to the problem of microbial pathogens in the ten years after the 1982 *E. coli* O157:H7 outbreak even though a 1985 report by the National Academy of Sciences concluded that the Agency's organoleptic inspection methods were inadequate to detect pathogens like *E. coli* O157:H7. *See* General Accounting Office, *Food Safety: Risk-Based Inspection and Microbial Monitoring Needed for Meat and Poultry*, GAO-94-110, at 5.

39. CDC, *Multistate Outbreak of* Escherichia coli *O157:H7 Infections Associated With Eating Ground Beef—United States, June-July 2002*, 51 MORBIDITY AND MORTALITY WKLY REP. (No. 29) 637, 638 (July 26, 2002), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5129a1.htm [hereinafter CDC].

40. *Id. See also* NESTLE, *supra* note 21, at 44-45 ("Animals from many locations arrive at the slaughterhouse together and remain in close contact until killed; their carcasses remain in close contact until processed. Contact alone favors the spread of pathogens.").

41. CDC, *supra* note 39, at 638.

42. *See id.*

43. Rangel et al., *supra* note 34, at 603.

44. Griffin & Tauxe, *supra* note 31, at 63

45. Robert V. Tauxe et al., *Foodborne Disease, in* MANDELL, DOUGLAS & BENNETT'S PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASE 1150, 1152 (5th ed. 2000). *See also* PROCEDURES TO INVESTIGATE FOODBORNE ILLNESS 107 (IAFP 5th ed. 1999)

common in children.[46] The duration of an uncomplicated illness can range from one to twelve days.[47] In reported outbreaks, the rate of death is 0-2%, with rates running as high as 16-35% in outbreaks involving the elderly.[48]

E. coli O157:H7 infections can lead to a severe, life-threatening complication called hemolytic uremic syndrome (HUS).[49] HUS accounts for the majority of the acute and chronic illnesses and deaths caused by the bacteria.[50] HUS occurs in 2-7% of victims, primarily children, with an onset of five to ten days after diarrhea begins.[51] It is the most common cause of renal failure in children.[52] Approximately half of the children who suffer HUS require dialysis, and at least five percent of those who survive have long term renal impairment.[53] The same number suffer severe brain damage.[54]

(identifying incubation period for *E. coli* O157:H7 as "1 to 10 days, typically 2 to 5"). In the Sizzler outbreak, the mean incubation period was 4.04 days, with a range of two to twenty-four days. Final Report, *supra* note 7, at 10.

46. Su & Brandt, *supra* note 30, at 705 (stating that "the young are most often affected").

47. Tauxe et al., *supra* note 45, at 1152.

48. *Id.*

49. *See* Griffin & Tauxe, *supra* note 31, at 65-68. *See also* Rangel et al., *supra* note 34, at 603 (noting that HUS is characterized by the diagnostic triad of hemolytic anemia—destruction of red blood cells, thrombocytopenia—low platelet count, and renal injury—destruction of nephrons often leading to kidney failure).

50. Beth P. Bell et al., *Predictors of Hemolytic Uremic Syndrome in Children During a Large Outbreak of* Escherichia coli *O157:H7 Infections*, 100 PEDIATRICS (No. 1) 1, 1 (July 1, 1997), *available at* http://www.pediatrics.org/cgi/content/full/100/1/e12.

51. Tauxe et al., *supra* note 45, at 1152. *See also* Nasia Safdar et al., *Risk of Hemolytic Uremic Syndrome After Treatment of* Escherichia coli *O157:H7 Enteritis: A Meta-analysis*, 288 J. AM. MED. ASS'N (No. 8) 996, 996 (Aug. 28, 2002) (stating that "[*E. coli*] serotype O157:H7 enteric infection has been recognized as the most common cause of HUS in the United States, with 6% of patients developing HUS within [two] to [fourteen] days of onset of diarrhea"); Amit X. Garg et al., *Long-Term Renal Prognosis of Diarrhea-Associated Hemolytic Uremic Syndrome: A Systematic Review, Meta-analysis, and Meta-regression*, 290 J. AM. MED. ASS'N (No. 10) 1360, 1360 (Sept. 10, 2003) ("Ninety percent of childhood cases of HUS are . . . due to Shiga toxin-producing *Escherichia coli*").

52. Su & Brandt, *supra* note 30, at 700.

53. Craig S. Wong et al., *The Risk of Hemolytic-Uremic Syndrome After Antibiotic Treatment of Escherichia coli O157:H7 Infections*, 26 NEW ENG. J. MED. 1930 (June 29, 2000), *available at* http://content.nejm.org/cgi/content/short/342/26/1930 (concluding that administration of antibiotics to children with *E. coli* O157:H7 appeared to put them at higher risk for developing HUS).

54. Richard L. Siegler, *Postdiarrheal Shiga Toxin-Mediated Hemolytic Uremic Syndrome*, 290 J. AM. MED. ASS'N (No. 10) 1379, 1379 (Sept. 10, 2003).

While rare, serious injury to the pancreas can also occur and may result in death or the development of diabetes.[55] Currently, no cure exists for HUS.[56] Tragically, as the parents of Brianna Kriefall can attest, many children with HUS die.[57]

The low infectious dose, coupled with the difficulty of combating the bacteria, make *E. coli* O157:H7 truly and decidedly deadly.[58] Unlike *Salmonella*, for example, which usually requires something approximating an "egregious food handling errors," *E. coli* O157:H7 found slightly undercooked in ground beef can result in infection.[59]

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55. Pierre Robitaille et al., *Pancreatic Injury in the Hemolytic-Uremic Syndrome*, 11 PEDIATRIC NEPHROLOGY 631, 632 (1997) (stating that "mild pancreas involvement in the acute phase of HUS can be frequent").

56. Nasia Safdar et al., *Risk of Hemolytic Uremic Syndrome After Antibiotic Treatment of* Escherichia coli *O157:H7 Enteritis*, 8 J. AM. MED. ASS'N 996 (Aug. 28, 2002); *see also* Siegler, *supra* note 54, at 1379 ("There are no treatments of proven value, and care during the acute phase of the illness, which is merely supportive, has not changed substantially during the past [thirty] years.").

57. Su & Brandt, *supra* note 30, at 700 (stating that "the mortality rate is 5 to10%"); *see also Kriefall*, 665 N.W.2d at 421 ("[T]hree-year-old Brianna Kriefall died from eating food that everyone party to this appeal . . . recognize[s] was cross-contaminated by *E. coli* O157:H7 bacteria from meat sold by Excel."). To gain insight into the impact of HUS on the parents of children who have died from an *E. coli* O157:H7 infection, read the speeches and testimony that can be found at the website for Safe Tables Our Priority (STOP), a non-profit grassroots organization devoted to advocacy of foodborne illness prevention through the public, media, government, and the scientific community, *at* http://www.safetables.org/Policy_&_Outreach/Public_Comments/index.html (last visited Jan. 23, 2006).

58. Griffin & Tauxe, *supra* note 31, at 72 ("The general patterns of transmission in these outbreaks suggest that the infectious dose is low."); V. K. Juneja et al., *Thermal Destruction of* Escherichia coli *O157:H7 in Hamburger*, 60 J. FOOD PROTECTION. (vol. 10). 1163-66 (1997) (demonstrating that, if hamburger does not get to 130°F, there is no destruction, and at 140°F, there is only a 2-log reduction of *E. Coli*).

59. Griffin & Tauxe, *supra* note 31, at 72 (noting that, as a result, "fewer bacteria are needed to cause illness than for outbreaks of salmonellosis"); NESTLE, *supra* note 21, at 41 ("Foods containing *E. coli* O157:H7 must be cooked at temperatures high enough to kill *all* of them.") (emphasis in original). The use of the term "undercooked" should be recognized as its tautology—i.e., undercooked means cooking food leaving enough bacteria to survive and to cause infection. While "undercooked" can imply negligence on the part of the person preparing the ground beef, especially as the term is used by the Meat Industry, this implication ignores the complexity of the heat destruction of this bacteria in a non-homogenous medium like ground beef. For example, after telling cooks for years to use color as an indicator of doneness, in June 1997, USDA issued a press release retracting its previous advice and recommended that a thermometer should be used to ensure "thorough" cooking. *See* FSIS Technical Publication, *Color of Cooked Ground Beef as it*

As few as twenty organisms have been said to be sufficient to infect a person and possibly even kill them.[60] And unlike generic *E. coli*, the O157:H7 serotype multiplies at temperatures up to 111°F sustains heat, resists drying, and can survive short exposures to acidic environments.[61]

To further an already dangerous threat, *E. coli* O157:H7 bacteria are easily transmitted by person-to-person contact.[62] A serious risk of cross-contamination between raw meat, ready-to-eat (RTE),[63] and raw vegetables and fruits exists, including the watermelons in the Sizzler outbreak.[64] Indeed, a primary criticism of USDA is the fact that the Agency has consistently failed to focus

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Relates to Doneness, available at http://www.fsis.usda.gov/oa/pubs/colortech.htm (citing the studies that prompted the changed recommendation). The USDA's current recommendations are still not without some learned and well-respected critics. *See, e.g.*, O. Peter Snyder Jr., *The Dangerous Bi-Metallic Coil Thermometer, available at* http://www.hi-tm.com/ Documents2001/hamburger-temp.pdf ("USDA-recommended bimetallic coil thermometer is an inaccurate, awkward, and complicated device for measuring the temperature of the highly contaminated, government-inspected and approved, raw foods that cooks must pasteurize.").

60. Patricia M. Griffin et al., *Large Outbreak of* Escherichia coli *O157:H7 Infections in the Western United States: The Big Picture, in* RECENT ADVANCES IN VEROCYTOTOXIN-PRODUCING ESCHERICHIA COLI INFECTIONS, at 7 (M.A. Karmali & A. G. Goglio eds. 1994) ("The most probable number of *E. coli* O157:H7 was less than [twenty] organisms per gram."). There is some inconsistency with regard to the reported infectious dose. *Compare* Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 683 (1998) (stating it can be "as few as ten") *with* NESTLE, *supra* note 21, at 41 (stating it can be "less than 50"). Regardless of these inconsistencies, everyone agrees that the infectious dose is, as Dr. Nestle has put it, "a miniscule number in bacterial terms." *Id.*

61. NESTLE, *supra* note 21, at 41.

62. Griffin & Tauxe, *supra* note 31, at 72. "The apparent ease of person-to-person transmission . . . is reminiscent of *Shigella*, an organism that can be transmitted by exposure to extremely few organisms." *Id.* As a result, outbreaks in places like daycare centers have proven relatively common. Rangel et al., *supra* note 34, at 605-06 (finding that 80% of the 50 reported person-to-person outbreaks from 1982-2002 occurred in daycare centers).

63. A RTE product is a product that is in a form that is edible without additional preparation and is not required to bear a safe-handling instruction. *See* 9 C.F.R. § 430.1 (2005).

64. Final Report, *supra* note 7, at 14 (concluding that "cross-contamination of fresh watermelon with raw meat product was the mechanism by which the vehicle became contaminated, and the raw sirloin tri-tips were the source of *E. coli* O157:H7 organisms in this outbreak"). Because litigation is still pending, it should be noted that Excel continues to deny that this conclusion as to causation is correct.

upon the risks of cross-contamination versus improper cooking.[65] With *E. coli* O157:H7, ultimately no real margin of error exists and the cost of error can be death.

B. Origins of the USDA's E. coli *O157:H7 Policy: Reactionary Rulemaking*

The history of food safety legislation and rulemaking in the United States is largely one of reaction. The first laws were prompted by the reaction to Upton Sinclair's *The Jungle* and its exposure of filthy conditions and practices in the meat-packing industry.[66] Since then, little has changed. As one commentator has aptly stated, "[t]he Jungle tipped off a century of charlatanism,

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65. *See, e.g.*, NATIONAL ACADEMY OF SCIENCE, Escherichia coli *O157:H7 in Ground Beef: Review of a Draft Risk Assessment*, Executive Summary, at 7 (noting that the lack of data concerning the impact of cross-contamination of *E. coli* O157:H7 during food preparation was a flaw in the Agency's risk-assessment), *available at* http://www.nap.edu/books/0309086272/html/7.

66. NESTLE, *supra* note 21, at 50-51 (stating that "complacency ended abruptly in 1906 when Upton Sinclair published his dramatic exposé of the meat industry"); Machado, *supra* note 15, at 802 (noting, somewhat hyperbolically, like much of the article that *The Jungle* "propelled an investigation . . . to quell public fears along with the mass hysteria that resulted"); Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 WILLAMETTE L. REV. 411, 446-47 (1997) (stating that *The Jungle* "graphically illustrated the unsanitary conditions of the meat packing industry . . . ultimately inspir[ing] Congress to enact legislation to provide for independent inspection of packing plants and slaughterhouses"); Roger I. Roots, *Other Rising Legal Issues: A Muckraker's Aftermath: The Jungle of Meat-Packing Regulations After a Century*, 27 WM. MITCHELL L. REV. 2413, 2420 (2001) ("Upon the precedent established by Sinclair's novel, federal inspection controls have ebbed and flowed along with periodic public outrages."); Delilah D. Schuller, *Pathogen Reduction Through "HACCP" Systems: Is Overhaul of the Meat Inspection System All It's Cut Out to Be?* 8 S.J. AGRI. L. REV. 77, 79 (1998) ("The exposé was the catalyst for the first federal meat industry reforms."); Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 79 (2000) ("The publication of Upton Sinclair's *The Jungle* helped persuade President Theodore Roosevelt to support, and Congress to pass the [Pure Food and Drug Act] and the [Meat Inspection Act] on the same day in 1906."); Neil D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L.J. 565, 584 (2003) ("The modern U.S. system of national food law began with enactments in Theodore Roosevelt's administration when public outrage vented on the meat industry after publication of Upton Sinclair's *The Jungle*."); Dion Casey, Comment, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J.L. & PUB. POL'Y 142, 143 (1998) ("*The Jungle* . . . sparked a public outcry which ultimately led to the passing of the Federal Meat Inspection Act.").

heavy-handed punditry, and political patronage in federal meat regulation. Upon the precedent established by Sinclair's novel, federal inspection controls have ebbed and flowed along with periodic public outrages."[67] As a consequence, the "federal regulatory system for food safety did not emerge from a comprehensive design but rather evolved piecemeal, typically in response to particular health threats or economic crises."[68] The end result has been a federal food safety system that has been described as "breathtaking in its irrationality."[69]

1. The 1992-1993 Multistate *E. coli* O157:H7 Outbreak: Dying for Change

One instance of a particular health threat sparking public outrage is the multi-state outbreak of *E. coli* O157:H7 infections that occurred from November 15, 1992 through February 28, 1993.[70]

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67. Roots, *supra* note 66, at 2420.

68. Statement of Robert A. Robinson, Managing Director, Natural Resources and Environment, *FOOD SECURITY AND SAFETY: Fundamental Changes Needed to Ensure Safe Food: Testimony Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Committee on Governmental Affairs*, GAO Report 02-47T, at 3 (Oct. 10, 2001), *available at* http://www.gao.gov/new.items/d0247t.pdf (remarking on the "resulting organizational and legal patchwork"). It was argued that "creating a single food safety agency to administer a uniform, risk-based inspection system is the most effective way for the federal government to resolve long-standing problems . . . and ensure the safety of the nation's food supply." *Id.* at 16.

69. NESTLE, *supra* note 21, at 55 (describing the system as "famously absurd," and noting that it is comprised of twelve agencies housed in six cabinet-level departments, coordination efforts governed by more than fifty inter-agency agreements). It is not surprising then that nearly all requests for reform of the federal food safety system advocate either the creation of a single federal food safety agency, or some form of increased consolidation. Merrill & Francer, *supra* note 66, at 66 and n.15 ("In the last fifty years, more than a dozen expert panels inside and outside government have called for the consolidation of the federal agencies that exercise and share food safety responsibilities."). Also not surprising is the near-uniform pessimism that such reforms will ever occur. *Id.* at 163 (concluding that consolidation is likely to remain merely an idea).

70. *Update: Multistate Outbreak of* Escherichia coli *O157:H7 Infections from Hamburgers—Western United States, 1992-1993*, 42 MORBIDITY AND MORTALITY WKLY REP. (No. 14) 258 (Apr. 16, 1993), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5129a1.htm (summarizing the findings from an ongoing investigation that identified a multistate outbreak resulting from consumption of one restaurant chain) [hereinafter Update]. This outbreak is nearly always referred

Initial reports indicated there were more than 500 laboratory-confirmed infections and four associated deaths that occurred in Washington, Idaho, California, and Nevada.[71] The State of Washington had made *E. coli* O157:H7 infections a reportable disease in 1987, and as a result, by 1993, most clinical laboratories had the ability to culture stools to detect the bacteria.[72]

The Jack in the Box outbreak was notable in many respects, not the least of which was the immense suffering that resulted; the outbreak was the largest outbreak of *E. coli* O157:H7 infections reported to date.[73] Over one-quarter of the outbreak victims were hospitalized, 7.5% developed HUS (mostly children), and four died.[74] With the benefit of only about one year of hindsight, one high-ranking CDC official wrote:

> The impact of this outbreak has been impressive. *E. coli* O157:H7 has become a household word. Food safety became a hot topic. National television and newspapers intensively covered the outbreak and its consequences. President Clinton was shown visiting an affected family. Parents of affected children gave presentations before U.S. government officials and on national television shows. And consumer groups, some newly formed because of the outbreak, became very involved in food safety.
>
> The impact on [USDA] has been unprecedented. It announced a Zero Tolerance program for fecal matter on raw beef carcasses, as

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to as the "Jack in the Box outbreak." *See, e.g.*, NESTLE, *supra* note 21, at 74 ("The consequences of the Jack in the Box outbreak were immediate."). The outbreak is so-called even though the implicated hamburger patties were extensively contaminated with *E. coli* O157:H7 during processing. *See* Bell et al., *supra* note 26, at 1352 (Nov. 2, 1994) (stating that "[a] large portion of 1 day's production of hamburger patties was contaminated with a single strain of *E. coli* O157:H7").

71. Update, *supra* note 70, at 258-61 (reporting that 477 persons met the case definition in Washington, fourteen in Idaho, thirty-four in California, and fifty-eight in Nevada, for a total of 583 cases). *See also* Griffin, *supra* note 60, at 7 ("Over 700 ill persons were reported, mostly children.").

72. Griffin et al., *supra* note 60 at 7-8 (noting that "this was different from the situation in the rest of the United States . . . and was important for the events that followed").

73. Bell et al., *supra* note 26, at 1353. The Jack in the Box outbreak would be surpassed three years later when approximately 10,000 people in Japan, including over 6,000 school children, were infected by eating contaminated radish sprouts. Yoshiyuki Watanabe et al., *Factory Outbreak of* Escherichia coli *O157:H7 in Japan*, 5 EMERGING INFECT. DIS. (No. 3) 424, 424 (May-Jun. 1999).

74. Griffin et al., *supra* note 60, at 7.

> well as a Pathogen Reduction Program. It also mandated safe handling labels for meat. It re-directed $5.7 million dollars [*sic*] of funds to food safety . . . . USDA's new focus on public health has been hotly contested by industry, and the final outcome is unknown.[75] Those who had long called for an overhaul of the meat inspection system caught the right wave of politics and problems, and the groundwork for HACCP was put into place.[76]

2. *E. coli* O157:H7: An Adulterant Per Se in Meat and Poultry

The fact that the Jack in the Box outbreak resulted in relatively prompt and significant changes to the federal food safety regulations, including the adoption of a HACCP-based meat inspection scheme, is widely acknowledged.[77] Of course, the Jack in the Box outbreak would certainly not be the last to prompt reactionary changes by USDA or other food safety agencies.[78]

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75. *Id.* at 12. *See also* NESTLE, *supra* note 21, at 90 ("In contrast, and rather a surprise in view of its past history, the USDA moved quickly [in the wake of the Jack in the Box outbreak] to introduce HACCP under the more consumer-friendly leadership appointed by President Clinton . . . . True to form, some meat industry groups objected.").

76. Roderick M. Hills Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, at 17, *available at* http://www.law.umich.edu/centersandprograms/olin/abstracts/discussionpapers/2003/Hills%2003007.pdf ("Like a surfer, the policy advocate has to wait for the right wave of problems and politics before he can move.") Mr. Hill argues, among other things, that "the best way to [focus] Congress' attention on the question of victim compensation is to force interest groups favoring preemption of tort claims to bear the burden of urging preemption of those claims before Congress." *Id.* at 37.

77. Johnson, *supra* note 6, at 164 (stating that the HACCP program "followed widespread publicity of an E. coli outbreak in 1993"); Fortin, *supra* note 66, at 581 (stating "it was only after public outrage and loss of consumer confidence that USDA finally acted to reduce *E. coli* O157:H7 contamination of meat products and proposed regulations to require meat HACCP—as the [National Academy of Science] had recommended a decade earlier"); Schuller, *supra* note 66, at 85 ("The [Jack in the Box] outbreak focused attention on the current meat-inspection system. Parents, consumer groups, even members of the meat industry pushed for reform. The government initially responded with promises of more inspectors. Ultimately, the government, with the help of others, developed and finalized HACCP."); Casey, *supra* note 66, at 148 ("It was only in the wake of this public outrage . . . that the USDA and the FSIS were finally prodded into action.").

78. *See, e.g.*, Deliganis, *supra* note 60, at 693 (discussing *E. coli* O157:H7 in the context of the Odwalla outbreak, which the author familiarly describes later in the article as "not just a story about the difficulties faced by one particular company, but rather a wake-up call to an entire industry"); Michael T. Roberts, *Mandatory Recall*

Nevertheless, at least initially, the regulatory changes prompted by the outbreak were significant. Foremost among the changes and the first to occur, was the USDA decision to declare *E. coli* O157:H7 as an adulterant within the meaning of FMIA. This USDA decision was the first time a foodborne pathogen on raw product was declared an adulterant under FMIA.[79]

One might reasonably assume that a declaration of such importance might have been promulgated as a regulation, or at a minimum be published in the Federal Register; however, this did not occur. Instead, on September 28, 1994, FSIS Administrator, Michael Taylor, announced that the Agency would begin treating any raw ground beef product bearing or containing *E. coli* O157:H7 to be adulterated within the meaning of FMIA.[80] The announcement was made in a speech given at the annual convention of AMI.[81] On October 11, 1994, the Agency circulated a "final draft" of a FSIS Notice stating how the ground beef sampling and testing program functioned as a way to detect *E. coli* O157:H7.[82] On October 19 that

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Authority: A Sensible and Minimalist Approach to Improving Food Safety, 59 FOOD & DRUG L.J. 563, 574-76 (discussing the ConAgra outbreak and recall and the widespread publicity and criticism that prompted calls for changes that, in characteristic fashion, FSIS largely shrugged off); CDC, Escherichia coli *O157:H7 Outbreak Linked to Commercially Distributed Dry-Cured Salami—Washington and California, 1994*, 44 MORBIDITY AND MORTALITY WKLY REP (No. 9) 157, 157-58 (Mar. 10, 1995), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ 00036467.htm (prompting USDA to enact regulations to ensure the safety of shelf-stable fermented sausages); FSIS Backgrounder, *FSIS Strategies for Addressing* Listeria monocytogenes, (Feb. 1999, updated May 2000), *available at* http://www.fsis.usda. gov/OA/background/bklisteria .htm (responding to *Listeria* outbreak in which several people died, stating that "FSIS is concerned about the recent, nationwide outbreak of listeriosis associated with meat and poultry products. The Agency believes this is an appropriate time to reconsider government and industry approaches to addressing *Listeria monocytogenes* in order to further reduce the risk of human illness.").

79. NESTLE, *supra* note 21, at 80 ("By the early 1990s, USDA officials had argued for two decades that . . . [it] did not have legal authority to set limits on microbial contaminants in meat and poultry because pathogens like *Salmonella* were 'inherent' in raw meat.").

80. *Id.* at 81.

81. *Id.*

82. FSIS NOTICE, Microbiological Testing Program for *Escherichia coli* in Raw Ground Beef (Final Draft, Oct. 11, 1994) (stating that "[t]o stimulate a reduction in the presence of [*E. coli*] O157:H7 in raw ground beef, FSIS will commence on October 17, 1994, a microbiological testing program for *E. coli* O157:H7") (on file with author). *See also* E-mail from from Robert A. LaBudde, President of Least Cost

same year, FSIS issued a "Constituent Alert" documenting Mr. Taylor's previous declaration concerning *E. coli* O157:H7 as an adulterant per se.[83] In addition to declaring that *E. coli* O157:H7 is an adulterant, the FSIS Notice also announced that it was going forward with a testing program for *E. coli* O157:H7 in ground beef.[84] As described by the court called upon to rule on the Agency's authority to institute the testing program:

> The notice announced that the FSIS would collect and test five thousand (5,000) samples of raw ground beef from federally-inspected establishments and retail stores. Any of these samples testing positive for the pathogen *E. coli* would be treated as "adulterated" under [FMIA] and referred to FSIS headquarters for regulatory action. Prior to this announcement, the USDA had treated pathogen-contaminated meat as unadulterated under the FMIA.[85]

Of course, in the absence of testing, the only way that USDA had an opportunity to learn about meat contamination was when an outbreak occurred.

While the announced testing program was specific to ground beef, it has never been clear that the agency considered *E. coli* O157:H7 to be an adulterant only in ground beef. For example, in the HACCP Final Rule, USDA stated that "some pathogens, such as [*E. coli*] O157:H7, are so virulent that a small number of organisms can pose a significant hazard.[86] Indeed, on that basis the agency has determined that any amount of [*E. coli*] O157:H7 will adulterate a meat or poultry product."[87] It was only in its later statements that USDA began to characterize—or, more accurately, recharacterize—its 1994 anouncement that *E. coli* O157:H7 was an adulterant per se as having applied solely to ground beef.[88]

Formulations, Ltd. since 1979, to the Author (Sept. 7, 2005, 11:40 PST) (on file with author) [hereinafter LaBudde E-mail].

83. LaBudde E-mail, *supra* note 82, at 1. After more than ten years of trying, the Author has still not been able to find a copy of the Constituent Alert in question.

84. *Id.*

85. Texas Food Industry Ass'n v. Espy, 870 F. Supp. 143, 145 (W.D. Tex. 1994).

86. HACCP Final Rule, 61 Fed. Reg. at 38,835.

87. *Id.* at 38,835.

88. *See, e.g.*, Non-Intact Meat Policy Statement, 64 Fed. Reg. 2803, 2803 ("In 1994, FSIS notified the public that raw ground beef products contaminated with pathogen [*E. coli*] O157:H7 are adulterated under the [FMIA]."). USDA-FSIS, *White Paper on* Escherichia coli *O157:H7*, Nov. 1999, Attachment to FSIS Constituent Update, November 5, 1999, *available at* http://www.nasda.org/joint/ecoli_paper.htm

Once announced, the meat industry predictably filed suit seeking a preliminary injunction to block the testing program on the grounds that it was not promulgated through appropriate rulemaking procedures, that it was arbitrary and capricious, and that it exceeded the USDA's regulatory authority under the law.[89] The court ruled that the USDA's decision to consider *E. coli* O157:H7 an adulterant was an "interpretative rule," and therefore not subject to the requirement of formal rulemaking.[90] The court then rejected the arguments that the rule was arbitrary and capricious, finding that:

> There is certainly a rational basis for the USDA to conduct some sort of testing in order to educate itself about this problem. Furthermore, the evidence indicates that the program has been at least partially successful in spurring industry to take greater preventive measures. Moreover, in light of the common cooking practices of most Americans, there is at least a rational basis for treating *E. [c]oli* differently than other pathogens. Finally, the court finds that [USDA's] changing policy is a rational response to an emerging problem.[91]

The court therefore accepted the rationale that, because ordinary cooking temperatures could not reliably eliminate *E. coli* O157:H7 from ground beef, USDA had good reason to deem the bacteria as an adulterant and to test for their presence.[92]

3. From "Command and Control" to HACCP: Shifting the Blame

With freedom comes responsibility, and such responsibility was placed with HACCP. The goal was to make the Meat Industry responsible for product safety and have FSIS move away from "command and control" to an oversight role. Such a shift of responsibility had been tried before without much in the way of success.[93] As a result of the public uproar and media attention

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("In 1994, FSIS declared that *E. coli* O157:H7 is an adulterant in ground beef and instituted a testing program for the pathogen.").

89. *Texas Food Industry Ass'n*, 870 F. Supp. at 145.

90. *Id.* at 147.

91. *Id.* at 148.

92. *See id.* at 149.

93. *See* Douglas C. Michael, *Cooperative Implementation of Federal Regulations*, 13 YALE. J. ON REG. 535 (Summer 1996) (describing how the mandatory HACCP

caused by the Jack in the Box outbreak, HACCP offered something different. FSIS would put in place a true science-based system to confront and finally solve the problem of microbial pathogens.[94] No longer would "poke-and-sniff" inspection systems suffice to protect the American public and its food supply.[95] All federally-inspected processors and slaughterhouses would be required to adopt HACCP systems to identify potential sources of pathogen contamination and establish procedures to prevent contamination.[96] According to USDA, "HACCP is the best system currently available for maximizing the safety of the nation's food supply."[97]

Explaining the elimination of regulations that had "assign[ed] to FSIS responsibility for the means used to produce safe food in a sanitary environment," the Agency announced:

> As part of its regulatory reform initiative, FSIS has undertaken the conversion of current command-and-control regulations to performance standards. Command-and-control regulations, and the Inspection System Guide that FSIS inspectors use to enforce those regulations, resulted from the perceived need to achieve uniformity among federally inspected meat and poultry establish-

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program proposed by FSIS was preceded by two different programs involving self-enforcement that achieved limited, if any, success). *See also* NESTLE, *supra* note 21, at 71-72 (describing the failure of the Agency's "streamlined" discretionary inspection program that it tried implementing from 1986-1989 before then abandoning it).

94. *See* 60 Fed. Reg. 6774, 6784 (Feb. 3, 1995).

95. *See id.*

96. HACCP Final Rule, 61 Fed. Reg. at 38,814 ("This final rule requires the federally-inspected establishments implements HACCP systems to address hazards that are reasonably likely to occur in their operations.") The publication of the HACCP Final Rule was preceded by the Proposed Rule, 60 Fed. Reg. 6774-6889 (Feb. 3, 1995). A discussion of the details of how HACCP is intended to work, and the specifics of the HACCP Final Rule is beyond the scope of this Article, and is, in any case, unnecessary given the more than adequate discussion of these subjects elsewhere. *See* Stephen R. Crutchfield et al. Economic Research Service/USDA, *An Economic Assessment of Food Safety Regulations: the New Approach to Meat and Poultry Inspection*, at 5-8 (AER-755 1997), *available at* http://www.ers.usda.gov/publications/aer755/ (situating the enactment of the HACCP Final Rule, summarizing what the Rule requires, and stating that the "new rules represent a comprehensive strategy on the part of FSIS to modernize the 90-year old inspection program"); Schuller, *supra* note 66, at 85-91 (providing a brief but thorough review of the history of HACCP and the requirements of the Final Rule); Fortin, *supra* note 66, at 566-68 (setting forth the seven HACCP principles, the development of HACCP in conjunction with NASA and detailing the superiority of it as a food safety system).

97. HACCP Final Rule, 61 Fed. Reg. at 38,814. *See also* Fortin, *supra* note 66, at 565 ("HACCP . . . is widely recognized as the best food safety system available.").

> ments. Technological advances introduce a new imperative, however. If establishments are to innovate, using new technologies to improve food safety, they cannot be impeded by a one-size-fits-all regulatory system. Under contemporary conditions, affording establishments the flexibility to make establishment-specific decisions outweighs the advantages of uniformly applicable rules.[98]

What was thus to result was a single regulation that created a non-uniform regulatory scheme. In effect, once implemented, HACCP plans would be the law of a given plant, but no other.

Moreover, "[u]nder the new system, industry assumes full responsibility for production decisions and execution."[99] And the regulations:

> represent a fundamental shift in FSIS's regulatory philosophy from, "command and control," to performance standards, which allow for more flexibility. Industry is being required by the regulation to develop plans for controlling food safety hazards that can affect their products. If the plans they design are effective in eliminating health and safety hazards, and if the establishment executes the plan's design properly, then the resulting product should be safe for consumers. Instead of FSIS determining the means by which establishments will meet their responsibility to produce safe, wholesome, and properly labeled products, FSIS will set performance standards that establishments must meet. This means that FSIS will no longer be attempting to, "inspect quality into a product." Inspection's role has become one of regulatory oversight.[100]

In short, FSIS inspectors will no longer be working "shoulder-to-shoulder" in the plant to ensure the safety and wholesomeness of the meat there produced. Rather, the inspectors will be looking *over* the shoulder of the meat industry as it tries to get it right. And the end

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98. *Id.* at 38,808 (emphasis added). The use of the passive voice in describing the "perceived" need for uniformity is telling in that it hides the fact that the perception was plainly shared by the Agency and the Meat Industry. That the disavowal of this perception was here passively described demonstrates the Agency's failure to take, at least in part, express responsibility for the past failure of its inspection scheme.

99. *Id.*

100. *Supervisory Guideline for the Pathogen Reduction/HACCP Regulatory Requirements*, at 2 (1998), *at* http://www.fsis.usda.gov/09/haccp/regreq98.pdf (last visited Oct. 21, 2005) [hereinafter HACCP Guidelines].

result, of course, at least in theory, is that it is not USDA's fault if unsafe meat makes it into distribution.

C. The Intact Meat Exception to the E. coli *O157:H7 Adulteration Standard: An Agency Apparently Recaptured*

The increased focus upon *E. coli* O157:H7 and meat safety began to erode not long after it started.[101] As one commentator stated, "when the outcry faded, the industries recaptured the agencies by pressuring the courts and Congress."[102] The Meat Industry, for example, was able to persuade USDA to exclude intact meat from its *E. coli* O157:H7 policy, treating such meat as unadulterated.[103] The resulting change in policy was, however, far from clear.

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101. NESTLE, *supra* note 21, at 84, 90-97 (describing the Meat Industry's ultimately unsuccessful efforts to derail the adoption of the Final HACCP Rule, while noting that it still managed to weaken the Rule and slow its adoption); Casey, *supra* note 66, at 150-54. *See also* Fortin, *supra* note 66, at 581 (stating that "the regulations were watered down before promulgation. Moreover, the meatpacking industry fought, and avoided, an effort to grant the government authority to order the recall of tainted food . . . . A number of writers argued that USDA retreated from its food safety mission in the face of [meat] industry pressure.").

102. Casey, *supra* note 66, at 142. *See also* Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PA. L. REV. 1027, 1064-68 (1990) (discussing Meat Industry capture of agency charged with regulating the Meat Industry); Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1182-84 (1994) (arguing that administrative agencies have limited resources available to properly and fully police product risks within their scope); Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1147-48 (1988) (discussing Meat Industry control of information needed by agency to regulate effectively hampers agency decision-making process).

103. Non-Intact Meat Policy Statement, 64 Fed. Reg. at 2803. The Meat Industry would no doubt disagree with any characterization of this new policy as a success, given the "shock, disbelief, and anger" that was expressed when it was first announced. NESTLE, *supra* note 21, at 103-04 (noting that "the reactions to this proposal demonstrated that the beef industry was determined to oppose any expansion of pathogen testing, no matter how limited or beneficial to the public"). However, the Meat Industry's subsequent embrace of the policy as being an exemption of substantial category of meat products from USDA's *E. coli* O157:H7 adulteration standards, and as a basis for federal preemption of state tort law, is but another example of how the Meat Industry tries to make victory from defeat.

Following *Texas Food Industry v. Espy*,[104] USDA stated in its Non-Intact Meat Policy Statement, published in the Federal Register on January 19, 1999, that the Agency believes the status under FMIA of beef products contaminated with *E. coli* O157:H7 must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed.[105] In its policy statement, the Agency provided no statutory basis for Agency authority to define adulteration on a product-specific basis. Nor did the Agency expressly state that *E. coli* O157:H7 was no longer an adulterant per se. Instead, it stated that:

> [USDA] believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product—*i.e.*, a food product that may be consumed safely without any further cooking or other preparation.[106]

Accordingly, based on the input it received, the Agency announced that it would consider expanding its sampling and testing program to include non-intact beef products or intact cuts of meat that are to be further processed into non-intact cuts.[107]

The corollary of the Agency's position was that, while it would treat non-intact meat as "adulterated" if contaminated with *E. coli* O157:H7, it would not treat intact meat as "adulterated" if it was identically contaminated.[108] Essentially, the Agency created an exception to its *E. coli* O157:H7 policy for an entire product-category—intact meat. The Agency defined the category as "cuts of muscle include steaks, roast, and other intact cuts (*e.g.*, briskets, stew beef, and beef 'cubes for stew', as well as thin-sliced strips of beef for

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104. 870 F. Supp. 143 (finding it reasonable to treat *E. coli* O157:H7 differently than other pathogens "in light of the common cooking practices of most Americans").

105. Non-Intact Meat Policy Statement, 64 Fed. Reg. at 2803.

106. *Id.* at 2804.

107. *Id.* ("The Agency may reconsider its sampling and testing program, as well as the scope of products deemed adulterated, in response to any comments received on the Agency's position regarding the application of the FMIA's adulteration standards.").

108. *Id.* (stating that "such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated.").

stir-frying) in which the meat interior remains protected from pathogens migrating below the exterior surface."[109]

The definition of "intact meat" is explicit in its reliance on the deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)[110] and the work it did for FDA and USDA in their joint development of the 1999 Food Code.[111] One such task was to determine the "appropriate cooking temperatures for, among other things, intact beef steaks for the control of vegetative enteric pathogens."[112] As stated in the Non-Intact Meat Policy Statement regarding intact product:

> Due to a low probability of pathogenic bacteria being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive heat to effect a complete sear across the cut surfaces . . . . The Committee's definition of "Intact Beef Steak" limited the applicability of this conclusion to "[a] cut of whole muscle[s] that has not been injected, mechanically tenderized, or reconstructed."[113]

Therefore, intact meat is any meat that is not non-intact, and vice versa.

Recognizing the utility of excluding entire product-categories from the USDA's *E. coli* O157:H7 policy, the Meat Industry soon began to press the Agency to also exclude mechanically-tenderized meat from the policy. The Meat Industry sponsored research intended to show the relative safety of this second category of meat products when cooked.[114]

In response to meat industry lobbying, the Agency asked NACMCF to "answer several questions with regard to *E. coli*

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109. *Id.*

110. Non-Intact Meat Policy Statement, 64 Fed. Reg. at 2803.

111. *Id.*

112. *Id.*

113. *Id.* at 2803-2804. *See also* 1999 Model Food Code, 3-201.11(E), *available at* http://vm.cfsan.fda.gov/~dms/fc99-3.html (defining "whole-muscle intact beef steaks" as those "that are intended for consumption in an undercooked form without a consumer advisory").

114. Wendy Warren, *Characterization of* E. coli *O157:H7 on Subprimal Beef Cuts Prior to Mechanical Tenderization: Project Summary* (Aug. 2002), *at* http://www.beef.org/uDocs/E.%20coli%20Mech%20Tenderization_Warren_6_6_03.pdf (stating on title page "Funded by America's Beef Producers") (last visited Jan. 11, 2006).

O157:H7 in blade-tenderized, non-intact beef."[115] For its part, "NACMCF concluded that non-intact, blade tenderized beef steaks could potentially contain an infective dose of *E. coli* O157:H7 in their interior."[116] As a result, on October 7, 2002, USDA announced in a policy statement that:

> FSIS is reviewing the NACMCF report and its draft risk assessment for *E. coli* O157:H7 in intact and non-intact (blade tenderized) steaks and will consider NACMCF's conclusions and the conclusions from the risk assessment with regard to the policy announced for non-intact products in the January 19, 1999 Federal Register . . . . At this time, FSIS believes that the public health hazard presented by *E. coli* O157:H7 and the prevalence of *E. coli* O157:H7 in these products continues to support application of the policy announced in the January 19, 1999, Federal Register. There is a lack of data on industry and consumer practices for cooking pinned, needled, and blade tenderized steaks (*e.g.*, grilling, oven broiling, or frying) and a lack of data on the proportion of [meat] industry outlets and consumers that prepare these products according to each of these different methods. If FSIS obtains substantial and reliable data showing that [meat] industry and consumers customarily cook pinned, needled, and blade tenderized products in a manner that destroys *E. coli* O157:H7, FSIS would consider modifications to its policy . . . in these products.[117]

As a result, the focus continued to be placed upon cooking and nothing else. The extremely low infectious-dose made cross-contamination as big a risk as undercooking. At least in the case of cross-contamination risk, the Agency remained steadfast in its position.

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115. E. Coli O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62,325, 62,333 (Oct. 7, 2002).

116. *Id.* This conclusion two years later proved correct, in the usual tragic fashion with this pathogen, when an outbreak of *E. coli* O157:H7 infections was linked to non-intact blade tenderized steaks. *See* Ellen Swanson Laine et al., *Outbreak of Escherichia coli O157:H7 Infections Associated with Nonintact Blade-Tenderized Frozen Steaks Sold by Door-to-Door Vendors*, 68 J. FOOD PROTECTION (No. 6) 1198, 1200, 1202 (2005) (describing an outbreak in which one fifty-two year-old HUS victim was hospitalized for twenty-five days and suffered permanent brain injury, and concluding that the "USDA should consider reevaluating the microbiologic hazards of technologies used in the production of nonintact steaks").

117. *Id.* at 62,334.

Thus, the focus continued to be placed upon cooking and nothing else when determining whether a category of meat products would be deemed adulterated. The extremely low infectious-dose made cross-contamination as big a risk as undercooking, but this was ignored. The responsibility for meat safety was undergoing another shift, this time from the Meat Industry to the consumer. After having first set forth a zero-tolerance policy for this deadly pathogen, because "any amount of [*E. coli*] O157:H7 will adulterate a meat or poultry product,"[118] the Agency now appeared in retreat.

III. KRIEFALL V. EXCEL MEAT CORPORATION: THE BATTLE FOR PREEMPTION BEGINS

The litigation that resulted from the Sizzler outbreak is exemplary in two ways. First, the outbreak itself is a perfect example of why the USDA *E. coli* O157:H7 policy on intact meat is evidence of agency capture, where "an agency moves too far toward accommodating a single interest while moving away from its statutory mission."[119] Second, the resulting litigation clearly demonstrated the Meat Industry's intent to invest whatever resources necessary to obtain an authoritative ruling that USDA regulations and policy statements can preempt state tort claims premised on an allegation that a meat product was unsafe and caused injury as a result.

A. The 2000 Sizzler E. coli *O157:H7 Outbreak: Cross-contamination Matters*

The Sizzler outbreak started with an outbreak of *E. coli* O157:H7 infections that occurred in the Milwaukee area six years ago. According to the outbreak investigation report issued by the Wisconsin Department of Health, over sixty-two confirmed cases were linked to food eaten at a local Sizzler restaurant.[120] Twenty-three individuals were hospitalized,[121] including four who developed

118. HACCP Final Rule, 61 Fed. Reg. at 38,835.

119. *See* Fortin, *supra* note 66, at 582 (pointing out that agency capture need not be blatant in that it "may provide a measure of public good, but regulators' care is balanced more for the industry's benefit than for the public's").

120. *See* Final Report, *supra* note 7, at 9.

121. *Id.*

HUS.[122] Tragically, one child, Brianna Kriefall died.[123] In addition to confirmed cases, there were 551 probable cases reported, linked by strong epidemiological evidence, and another 122 possible cases.[124]

In an attempt to explain how this huge outbreak occurred, the State Department of Health set forth its conclusions with surprising directness:

> Based on the results of the case-control study, the test results of the opened and intact food samples from the restaurant and the conclusions of the restaurants inspections, it is most probable that the watermelon was the vehicle for infection, cross-contamination of fresh watermelon with raw meat product was the mechanism by which the vehicle became contaminated, and the raw sirloin tri-tips were the source of *E. coli* O157:H7 organisms in this outbreak.[125]

An extension of the scientific conclusions, however, remains the human element; there lies the real tragedy, and death. As the mother of Brianna Kriefall put it, "Our daughter was a miracle child we waited eight years for. And now she's gone, and we'll never get her back."[126]

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122. *Id.*

123. *See id. See also* Joby Warrick, *An Outbreak Waiting to Happen: Beef-Inspection Failures Let In a Deadly Microbe*, WASH. POST, Apr. 9, 2001, at A1 (reporting that:

> Wisconsin health investigators later concluded Brianna Kriefall died from eating watermelon that Sizzler workers had inadvertently splattered with juices from tainted sirloin tips. The meat came from a Colorado slaughterhouse where beef repeatedly had been contaminated with feces, [*E. coli*]'s favorite breeding ground. Federal inspectors had known of the problems at the plant and had documented them dozens of times. But ultimately they were unable to fix them.).

124. Final Report, *supra* note 7, at 9.

125. *Id.* at 14. This was not the first time that cross-contamination between raw meat and other food items had caused an outbreak of *E. coli* O157:H7 infections at a Sizzler restaurant. *See, e.g.*, Lisa A. Jackson et al., *Where's the Beef? The Role of Cross-Contamination in 4 Chain Restaurant Associated Outbreaks of* Escherichia Coli *O157:H7 in the Pacific Northwest*, 160 ARCHIVES OF INTERNAL MED. 2380, 2385 (Aug. 14, 2000) (finding that "relatively subtle lapses in food-handling procedures might be sufficient to result in an outbreak," and that "[t]hrough cross-contamination, meat can be a source of *E. coli* O157:H7 infection even if it is later cooked properly").

126. Warrick, *supra* note 123, at A1.

B. The Start of Litigation

The first lawsuit was filed on August 1, 2000, naming the Sizzler franchisor as the defendant.[127] The complaint was amended on August 24, 2000 to add the Excel Corporation as a defendant.[128] Among its allegations, the First Amended Complaint alleged that Excel "manufactured meat contaminated with *E. coli* O157:H7, and that this meat was used in the preparation of food at the Sizzler restaurant . . . and was the source of the bacteria that injured the plaintiff, Ervin Lesak, and caused his *E. coli* O157:H7 infection."[129] Based on this and other allegations, the plaintiffs asserted four state law claims: (1) strict liability, (2) negligence per se, (3) negligence, and (4) breach of warranty.[130]

Instead of filing an answer, Excel removed the actions to federal court pursuant to 28 U.S.C. § 1442(a)(1). The statute was enacted because "Congress has decided that federal officers, and indeed the Federal Government itself, require the protection of a federal forum."[131] Excel alleged that its plants were, in fact, an extension of the federal government, that its employees were government agents, and that removal was proper because the "amount of federal oversight, regulation, supervision and control exerted by FSIS over Excel is as pervasive as it is complex."[132] Excel further argued that Congress has empowered FSIS to supervise and control meat production facilities, while enforcing its detailed and comprehensive regulatory scheme, to protect the health and welfare of consumers, create uniform national standards, and to eliminate burdens to interstate commerce. Because Excel conducts virtually all of its day-to-day operations pursuant to the detailed supervision and control of FSIS, plaintiffs' claims against Excel will directly interfere with the operation of FMIA and FSIS's implementation of its corresponding

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127. Complaint, Lesak v. E & B Mgmt. Co., Waukesha Inc. et al., No. 00-CV-006360 (Aug. 1, 2000).

128. First Amended Complaint, *Lesak v. Excel Corp. et al.*, No. 00-CV-006360 (Aug. 24, 2000).

129. *Id.* at 5.

130. *Id.* at 4-9.

131. Willingham v. Morgan, 395 U.S. 402, 407 (1969). The Court also noted that, historically, "the removal provision was an attempt to protect federal officers from interference by hostile state courts." *Id.* at 405.

132. Notice of Removal, at 3, *Lesak v. E & B Mgmt. Co. Waukesha, Inc.* et al., No. 00-CV-006360, (Nov. 28, 2000) [hereinafter Notice of Removal].

federal policies.[133] According to Excel, as a matter of law it was entitled to a federal forum because its operation of a USDA-inspected meat processing facility made it "directly involved in the implementation of federal policy."[134] In short, according to Excel, it was essentially a government contractor.

The United States District Court Judge Charles N. Clevert rejected Excel's arguments, and its description of pervasive control and direct physical supervision. The court stated, "Notwithstanding Excel's representations regarding the presence of federal officials in its plant, it does not appear that the FMIA or the FSIS exercises the type of control or supervision justifying removal."[135]

The court also rejected Excel's attempt to make the possibility of federal preemption a basis for removal. The court wrote:

> Because Excel did not meet its burden in demonstrating that it was acting under an agency or officer, the court need not decide whether it has a colorable federal defense to the plaintiffs' claims. A significant portion of Excel's oversized brief focuses on this defense. That Excel might ultimately prove that plaintiffs' claims are [preempted] does not establish that they are removable to federal court.[136]

The court thus ruled that Excel had failed to satisfy its burden of establishing the existence of removal jurisdiction.[137] As a result, Excel was forced to make its preemption argument in state court—a forum that it had wrongly assumed would be hostile to its arguments.

C. Excel's Motion for Summary Judgment and the Opposition to It

Excel's Notice of Motion and Motion for Summary Judgment were filed on February 22, 2002, along with a supporting Memorandum of Law.[138] The argument Excel made was exceedingly

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133. *Id.* at 4 (citing 21 U.S.C. § 601 (2000).

134. *See* Notice of Removal, *supra* note 132, at 3.

135. *Lesak v. E & B Mgmt. Co. Waukesha, Inc. et al.*, No. 00-C-1508, at 8 (E.D. Wis. Apr. 30, 2001) (granting plaintiffs' motion to remand).

136. *Id.* at 11 (citing Caterpillar Inc. v. Williams, 482 U.S. 386, 392 (1987)).

137. *See id.*

138. Excel Corporation's Notice of Motion, Motion for Summary Judgment, and Memorandum of Law in Support of Summary Judgment, *In re Consolidated E. coli O157:H7 Cases*, No. 00-CV-006503 (Milwaukee Cir. Ct. May 15, 2002) [hereinafter as Excel's Memorandum].

simple, and essentially captured the following points: (1) only USDA (and not the States) can define what constitutes "adulterated" within the meaning of FMIA; (2) USDA does not deem "intact products that are to be distributed for consumption as intact products" as "adulterated" within the meaning of FMIA if surface-contaminated with *E. coli* O157:H7; (3) the Excel meat contaminated with *E. coli* O157:H7, which caused the outbreak that gave rise to the present lawsuit, were intact cuts of meat when distributed; and therefore, (4) Wisconsin state law is preempted to the extent that it treats as "adulterated" what USDA, as the agency charged with interpreting FMIA, has decided not to so treat.

The argument that Wisconsin law was preempted was supported by a lengthy discussion of express preemption, based primarily on a Michigan Court of Appeals case, *Boulahanis v. Prevo's Family Market*,[139] and the critical need for national uniform standards and deference to the USDA's determination that *E. coli* O157:H7 was not an adulterant when present on meat that was intact at the time it left the federally-inspected establishment.[140] Summarizing its position, Excel hit all the points the Meat Industry would emphasize throughout the litigation. It wrote:

> Given the importance of preserving the integrity of our national food supply, the federal government has spent decades developing extensive regulations and uniform national standards governing every aspect of the production and distribution of meat in interstate commerce . . . .
>
> The uniform national standards governing the production of raw meat expressly provide that whole-intact meat containing *E. coli* may be distributed for consumption in interstate commerce. This is because, although pathogenic bacteria (such as *E. coli*) occurs naturally in the production of meat (and is virtually impossible to avoid, safe food-handling readily destroy the bacteria. Instead of requiring meat producers to do the impossible (by completely eliminating pathogenic bacteria), the federal government relies on the end-user to follow safe food-handling practices to avoid the dangers associated with raw meat.[141]

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139. 583 N.W.2d 509, 512 (1998) *cert. denied* 530 U.S. 1203 (2000) (holding ground beef containing *E. coli* O157:H7 was not defective under state law because USDA had not declared it an adulterant under FMIA).

140. Excel Memorandum, *supra* note 138, at 2-3.

141. *Id.* at i-ii.

In short, according to Excel and its Meat Industry cohorts, the federal government affirmatively authorized the distribution of meat contaminated with *E. coli* O157:H7, and provided that it was the consumer's responsibility to ensure the safety of the meat consumed.

The plaintiffs argued that (1) the Non-Intact Meat Policy Statement was an interpretive rule that could not preempt state law, (2) there was a question of fact whether the tri-tips implicated in the Sizzler outbreak were non-intact meat within the meaning of Agency policy, and (3) the court owed no deference to a policy that irrationally treated non-intact meat further processed in a federally-inspected establishment different than that further processed at retail (like that which happened at the Sizzler restaurant).[142] The latter argument was premised on the notion that USDA could not, within the authority delegated to it, interpret the meaning of "adulterated" under FMIA in a way that was inconsistent with the intent of the Act to protect the public from unsafe and unwholesome meat.[143]

D. The Trial Court Grants Excel Summary Judgment on all Claims

The order granting Excel's Summary Judgment Motion was signed and filed on May 15, 2002.[144] The circuit court granted summary judgment because it agreed with Excel that Congress had delegated to the USDA the exclusive role of determining when meat is safe and unadulterated.[145] Moreover, the court found that, in its Non-Intact Meat Policy Statement, USDA had determined that "intact meat containing surface *E. coli* O157:H7 bacteria should not be considered adulterated under federal law because the bacteria is destroyed when the surface of the intact cuts are broiled in

142. Memorandum in Opposition to Summary Judgment, *In re Consolidated* E. coli *O157:H7 Cases*, No. 00-CV-006503, at x-xiv, and 10-18 (Milwaukee Cir. Ct., May 15, 2002).

143. *Id.* at 18 and n.22 (stating that "even if the FSIS had intended to issue such a policy [as that alleged by Excel], and assuming *arguendo* that it has the legal authority to do so, this [c]ourt would be bound to reject it") (emphasis in original).

144. *In re Consolidated* E. coli *O157:H7 Cases*, No. 00-CV-006503 (Milwaukee Cir. Ct. May 15, 2002) (granting summary judgment dismissing all claims).

145. *Id.* at 2 (noting that "[p]art of the USDA's job is to determine when meat is 'safe, wholesome, and not adulterated.'") (quoting Armour & Co. v. Ball, 468 F.2d 76, 81 (6th Cir. 1972)).

establishments like Sizzler's Steak House."[146] This meant that the plaintiffs were barred from bringing a civil suit against a meat processor like Excel because "Congress has expressly preempted the states from establishing meat standards different from federal ones."[147] Consequently, the court concluded that the express preemption provision in the FMIA "overcomes any state law to the contrary."[148] Explaining its conclusion, the court stated the following:

> The policy behind preemption in this area makes sense. Excel's processing plant is an "official establishment" governed by the Federal Meat Inspection Act. The federal government has acted in this area to provide national standards so that properly handled and cooked meat products are safe for human consumption. These standards protect the meat processors also, so that they know what is expected of them in regard to their products that are distribute[d] among the many states. In an area of such great national concern, it is essential that the rules be uniform. Federal inspectors are in these meat plants, testing the meat and monitoring the processing programs of companies like

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146. *Id.* (citing 64 Fed. Reg. 2803, 2804 (1999)). The court went on to quote the Non-Intact Meat Policy Statement to the effect that "[i]ntact steaks, and other cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed." *Id.* The court did not address, however, the fact that the case did not involve persons injured by the consumption of surface-contaminated meat. Thus, like USDA, the court ignored the implications of the risk of cross-contamination on the determination of whether meat should be deemed adulterated. One can only speculate whether the court's approach might have differed if Excel had been the only available defendant. The court suggested as much at the end of its decision when it wrote that "[i]t is important to note that this decision does not deny the plaintiffs their day in court. They may continue against the restaurant whose employees handled the food as well as against the restaurant's national franchisor, who is alleged to have improperly trained and supervised its local franchisee." *Id.* at 3.

147. *Id.* at 2. As quoted by the court, the FMIA preemption clause reads in pertinent part:

> Requirements . . . with respect to premises, facilities and operations of any establishment . . . which are in addition to, or different than those made under this chapter may not be imposed by any State . . . Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State . . . .

21 U.S.C. § 678 (2000).

148. *In re Consolidated* E. coli *Cases*, No. 00-CV-006503, at 2 (citing *Boulahanis*, 583 N.W.2d at 511-12).

> Excel. The federal regulatory scheme is so long-standing and so comprehensive that I conclude it preempts any state laws to the contrary. That includes bringing civil suits against meat processors like Excel.[149]

To call the trial court's ruling on Excel's motion for summary judgment a clear victory for the Meat Industry would, by any measure, be an understatement. This victory would prove short-lived, however. The Court of Appeals proved a much more skeptical audience.

E. The Wisconsin Court of Appeals Reverses: Reopening the Courthouse Doors

In reversing the trial court's grant of summary judgment to Excel, the Court of Appeals first set forth the most important fact, and defined the issue before it:

> In July of 2000, a number of persons were injured and three-year old Brianna Kriefall died from eating food that everyone party to this appeal, the plaintiffs, Sizzler USA, and Excel, recognize was cross-contaminated by E. coli O157:H7 bacteria from meat sold by Excel. Although some of the parties' arguments on appeal focus on both to what extent the E. coli contamination was a cause of Brianna's death and the other injuries, and whether Excel was either negligent or sold a dangerously defective product, the only issue we need decide on this appeal is whether the claims against Excel are preempted by federal law.[150]

The court then announced its decision "that federal preemption does not close the doors of Wisconsin's courts to the claims against Excel."[151]

After summarizing the basics of preemption analysis, the court turned to the question of whether state tort claims were "requirements . . . with respect to premises, facilities and operations" within the meaning of FMIA's preemption clause.[152] Instead of answering the question, however, the court "assume[d], without deciding, that the word 'requirements' encompasses state common-

149. *Id.* at 2-3.
150. *Kriefall*, 665 N.W.2d at 421.
151. *Id.*
152. *Id.* at 422-23 (citing 21 U.S.C. § 678).

law claims, although the law on this is not yet entirely settled."[153] The court noted that the United States Supreme Court in *Medtronic, Inc. v. Lohr*[154] had failed to resolve the question, even though some courts incorrectly referred to Justice Steven's plurality opinion, rejecting the view "that any common-law cause of action is a 'requirement' which alters incentives and imposes duties 'different from, or in addition to,'" the applicable federal standard, as having stated the view of the Court.[155]

The court continued its analysis, as it should have, by addressing "Congressional intent concerning the interstate sale of meat."[156] Noting that Congress had intended FMIA to accomplish more than one thing, the court concluded that the "overriding congressional purpose is . . . public-safety—as evidenced by not only the section's direct statements to that effect but also by one of the stated rationales underlying the concurrent congressional desire to preserve fair competition for those who sell wholesome and properly packaged and labeled meat."[157]

Having identified public safety as the primary purpose of FMIA, the court next turned to its preemption analysis. First, it noted that FMIA did not have an "all-encompassing clause" that delegated to the Secretary authority to make such rules and regulations necessary to carry out the provisions of the Act.[158] The court therefore concluded that:

> [A]lthough the Secretary has a wide berth in implementing the congressional mandate to inspect meat-processing plants, the

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153. *Id.* at 422 n.3. The court also assumed, without deciding, that if the "claims asserted here against Excel would, if successful, affect Excel's 'operations' by encouraging Excel to change those 'operations' in order to avoid future liability caused by *E. coli* contaminated meat." *Id.* at 423 n.3. This assumption is only true, however, if one also assumes that the change made to the operation would be intended to improve the safety of the meat produced, because that would be the only way to avoid future liability. As is discussed in Section IV, effecting such improvements is a strong argument against preemption because civil lawsuits are an important incentive for food safety innovation and investment.

154. 518 U.S. 470 (1996) (holding that, absent an express congressional statement to the contrary, federal law did not preempt general common law duties).

155. *Kriefall*, 665 N.W.2d at 422 n.3.

156. *Id.* at 423 (citing 21 U.S.C. § 602).

157. *Id.* at 424.

158. *See id.* at 424. "In contrast to some other delegations of authority by Congress to administrative agencies, Congress's delegation here is focused." *Id.* at 425.

> Secretary has only limited authority to affect the congressional definition of "adulterated," other than in the area of labeling (21 U.S.C. § 601(m)(5), (7)-(9)). And that limitation . . . is critical in this case because of Excel's argument that the Secretary views intact meat contaminated with [*E. coli*] O157:H7 as not "adulterated."[159]

The question then became whether the Secretary's treatment of *E. coli* O157:H7-contaminated intact meat as not "adulterated" was consistent with the Congressional definition of the term and the intent of FMIA.

Answering this question, the court noted that the "[*E. coli*] strain that killed Brianna and made others sick is a 'deleterious substance which *may* render [meat] injurious to health.' There is no dispute about this."[160] It further noted that meat is, by definition, "adulterated" if it "bears or contains" *E. coli* O157:H7—a deleterious substance.[161] This meant, the court said, intact meat contaminated with *E. coli* O157:H7 is "adulterated" within the meaning of FMIA even if it "can be rendered *non*-'injurious to health' by cooking thoroughly."[162]

The court also rejected Excel's contention that it was legally significant that the meat arrived at the Sizzler restaurant as intact cuts of meat and that the boxes containing the meat bore warning labels.[163] As the court pointed out, Excel was required by the HACCP Final Rule to consider "the intended use or consumers of the finished product."[164] In the case of the Sizzler outbreak, it was the intended use of the meat products—i.e., the cutting and mechanically-tenderizing of the meat into steaks—that was said to have been the cause of the outbreak.[165] Therefore, it could not be said that the presence of *E. coli* O157:H7, even on the surface of the meat, complied with the regulations Excel had invoked as the basis for preemption.[166] In other words, you could not use a regulatory

159. *Kriefall*, 665 N.W.2d at 425.

160. *Id.* at 425 (citing 21 U.S.C. § 601(m)(1) (emphasis and bracketed material in original).

161. *See id.* at 426.

162. *Id.* (emphasis in original).

163. *Id.* at 428.

164. *Kriefall*, 665 N.W.2d at 428 (citing 9 C.F.R. § 417.2(a)(2)).

165. *See* Final Report, *supra* note 7, at 13.

166. *See Kriefall*, 665 N.W.2d at 428 (stating that "to be able to determine the adequacy of their [hazard-analysis] plans, establishments that produce intact beef products need to determine whether their products will be used to produce raw,

standard to preempt a state tort claim based on it if you had not, in fact, complied with the standard.

Despite reaching a point in its analysis that might have by itself been dispositive of the issue, the court continued to conduct an exhaustive analysis of the USDA's adoption and implementation of a HACCP-based inspection system to determine if the fact of such inspection impliedly preempted the plaintiffs' claims.[167] The court began by stressing that FSIS had "delegated to the meat processors themselves the responsibility of coming up with procedures . . . adapted to the processors' own circumstances, to safeguard the wholesomeness of the meat they produce."[168] This fact alone belied Excel's assertions that preemption was necessary to preserve uniform, national regulations. As the court stated:

> [I]nsofar as the preemption doctrine implicates a federal need for uniformity of regulation . . . ,the federal inspection scheme here *eschews* uniformity in favor of non-uniform plant-by-plant Hazard Analysis and Critical Control plans developed by the plant operators themselves. Simply put, rather than a nation-wide uniform, one-size-fits-all approach present in so many preemption cases, the Food Safety and Inspection Service now lets meat processing plants monitor themselves with only comparatively minimal federal oversight.[169]

In the absence of a countervailing need for uniformity, the court concluded that "a claim premised on damages resulting from the sale of 'adulterated' meat," in the words of *Medtronic*, "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."[170]

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non-intact product.") (quoting *E. coli* O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62,325, 62,329 (Oct. 7, 2002)). How USDA expects establishments to make this determination has never been explained, given that, except for product being sent to another federal establishment for further processing, intact meat products could presumably end up anywhere for further processing. Of course, with regard to subprimals, like the tri-tips implicated in the Sizzler outbreak, which average three to five pounds each, one might always safely assume that further processing of some kind is going to occur.

167. *Kriefall*, 665 N.W.2d at 429-33.

168. *Id.* at 429.

169. *Id.* at 435 (emphasis in original; citations omitted).

170. *Id.* at 434 (quoting *Medtronic*, 518 U.S. at 495). *Accord Bates et al. v. Dow Agrosciences*, 544 U.S. __, 125 S. Ct. 1788, 1802 (2005) (holding that state law tort claims were not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and finding that "[p]rivate remedies that enforce federal misbranding

Finding that USDA had used its delegated power to declare *E. coli* O157:H7 as an adulterant per se in all raw meat products, and that it "consider[ed] an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level,"[171] the court rejected Excel's argument that USDA authorized it to distribute contaminated meat just because the meat was intact at the time it left its meat-processing facility. In doing so, it deferred to the USDA's recognition of the "intolerable public health problem"[172] posed by *E. coli* O157:H7, and the fact that if its "presence can be prevented, no amount of temperature abuse, mishandling or under-cooking can lead to foodborne illness."[173] What the court called the USDA's zero-tolerance policy for *E. coli* O157:H7 was therefore upheld—much to Excel's displeasure.[174]

F. Attacking the Kriefall Decision and Seeking to Overturn It

The Meat Industry pulled out all the stops seeking to have the *Kriefall* decision overturned, first petitioning the Wisconsin Supreme Court, and then the United States Supreme Court. It cannot be said, of course, that this denial of further review is an affirmative upholding of the Court of Appeal's analysis, since factors other than the correctness of a ruling can dictate whether review is granted.[175]

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requirements would seem to aid, rather than hinder, the functioning of FIFRA"). Writing for the majority, Justice Stevens, in terms plainly applicable to the Meat Industry's position in *Kriefall*, criticized the defendant for "greatly overstat[ing] the degree of uniformity and centralization that characterizes FIFRA." *Kriefall*, 665 N.W.2d at 434.

171. *Id.* at 432 (citing Contamination of Beef Products, 67 Fed. Reg. 62,325, 62,329 (Oct. 7, 2002) (codified at 9 C.F.R. pt. 419)).

172. *Id.*

173. *Id.* (citing HACCP Final Rule, 61 Fed. Reg. at 38,962).

174. Whether there is a zero-tolerance policy for *E. coli* O157:H7 is arguably open to question, but only because USDA utterly fails to speak clearly on the subject. If forced to, USDA very likely might state that it does not have a zero-tolerance policy for *E. coli* O157:H7 on all meat products. That the court in *Kriefall* nevertheless managed to ably build the case for the existence of a zero tolerance *E. coli* O157:H7 policy "concomitant" with "what the agency called 'zero tolerance' for fecal contamination," *Kriefall*, 665 N.W.2d at 435, should be proof enough that Agency policy is far from sufficiently clear.

175. *See, e.g.*, WIS. STAT. § 809.62(1) ("Supreme Court review is a matter of judicial discretion, not of right, and will be granted only when special and important reasons are presented."). Excel sought review from the Wisconsin Supreme Court on two bases: that the case presents a "significant question of federal preemption,"

However, the *Kriefall* decision was not overturned, and to that extent, its holding and analysis now stand as precedent in Wisconsin, ans as persuasive authority elsewhere. The same thing cannot be said of the arguments made by the Meat Industry, all of which were rejected, and which can be summarized as follows.

1. The FMIA's Preemption of State Law is Well-Settled, and USDA's Power to Promulgate Adulteration Standards is Virtually Unlimited

The Meat Industry claimed that "courts interpreting [FMIA] have concluded that FSIS enjoys broad rulemaking authority," and that this broad grant of authority "enables the agency to issue uniform national standards for meat products."[176] While the Meat Industry's position was replete with citations to case-law, including sixteen decisions of the United States Supreme Court,[177] only one cited case involved the issue of FMIA preemption of state law tort claims, *Boulahanis v. Prevo's Family Market*.[178] Yet, as the Court of Appeals pointed out, the *Boulahanis* case was "irrelevant to our decision."[179] Additionally, no single published court opinion held that FMIA or the rules promulgated pursuant to it preempts state tort claims involving beef products. All of the other FMIA preemptions cases cited by Meat Industry dealt with misbranding.[180]

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and that the "court of appeals' decision conflicts with the decisions of the United States Supreme Court and of other courts." *See* Petition for Review, at 4-27, *Kriefall*, 671 N.W.2d 849 [hereinafter Petition for Review].

176. *See* Petition for Review, at 21, *Kriefall*, 671 N.W.2d 849.

177. Petition of Review, at i-ii, *Kriefall*, 671 N.W.2d 849.

178. 583 N.W.2d 509 (Mich. Ct. App. 1998) *cert. denied* 530 U.S. 1203 (2000) (holding that FMIA preempted state claims for injuries caused by the sale of ground beef contaminated with *E. coli* O157:H7). The reliance on *Bouhalanis* was strange, and almost wistful—like a fan of the Chicago Cubs consoling itself after another lost pennant race with a reminder that the team had in fact won a World Series at least once before. Near-nostalgically, *Bouhalanis* is a reminder that there was once no *E. coli* O157:H7 rule and no USDA retail sampling program.

179. *Kriefall*, 665 N.W.2d at 436 (criticizing the decision for the "paucity of its analysis" and questioning whether finding preemption in agency inaction was viable in light of the United States Supreme Court's *Sprietsma* decision).

180. *See* Petition for Review, at 25-27 (citing Jones v. Rath Packing Co., 430 U.S. 519 (1977) (holding that state law pertaining to the labeling by weight of packaged foods at retail was is in conflict with, and preempted by, FMIA; *see also* National Broiler Council v. Voss, 44 F.3d 740 (9th Cir. 1994) (holding California law that regulated the use of the term "fresh" on labels for poultry was preempted by Poultry

The only other cases cited by the Meat Industry were equally misplaced because none of them involved FMIA section 601(m)(1), the definition of "adulterated" at issue in the case.[181]

Products Inspection Act); Pacific Trading Co. v. Wilson & Co., 547 F.2d 367 (7th Cir. 1976) (affirming without discussion the dismissal of claims in a breach of contract action that alleged private right of action for civil damages based on violation of several federal laws, including FMIA); *Armour & Co. v. Ball*, 468 F.2d 76, 88 (6th Cir. 1972) (holding that Michigan labeling requirement for sausages were preempted because "Congress has unmistakably so ordained . . . preemptive language provides 'marking, labeling . . . or ingredient requirements'" prescribed by the Secretary preempt this field of commerce.); *American Nw. Selecta, Inc. v. Munoz*, 106 F. Supp. 2d 223 (D. Puerto Rico 2000) (holding that regulation that required poultry inspection date to appear on federal inspection certificate was invalid as in conflict with federal regulations on official marks and certificates); Mario's Butcher Shop & Food Ctr. v. Armour & Co., 574 F. Supp. 653 (N.D. Ill. 1983) (discussing in dictum FMIA preemption while holding that a violation of federal "misbranding" laws could support a claim under the Illinois Deceptive Practices Act).

181. *See* Petition for Review, at 21-23, *Kriefall*, 671 N.W.2d 849 (citing Michigan Meat Ass'n v. Block, 514 F. Supp. 560 (W.D. Mich. 1981) (holding that the FMIA did not violate the plaintiffs' Fifth Amendment substantive due-process rights); *see also* American Trucking Ass'ns v. United States, 344 U.S. 298 (1953) (interpreting road safety rules promulgated by the Interstate Commerce Commission pursuant to the Motor Carriers Act of 1935); Houston v. St. Louis Indep. Packing Co., 249 U.S. 479 (1919) (upholding USDA regulation prohibiting use of the term "sausage" as false and deceptive when applied to products with added cereal in-excess of two-percent and added-water in-excess of three-percent); Grocery Mfrs. of Am. v. Gerace, 755 F.2d 993 (2d Cir. 1985) (addressing federal labeling requirements for alternative cheese products and meat product containing them); Community Nutrition Inst. v. Block, 749 F.2d 50 (D.C. Cir. 1984) (upholding USDA labeling regulations under Section 610(d) allowing the use of mechanically de-boned meat in processed meat food products with a label that described bone content in terms of the calcium the product contained); Public Citizen v. Foreman, 631 F.2d 969 (D.C. Cir. 1980) (affirming district court ruling that nitrites in bacon and other cured meats are exempt from the provisions of the FDCA); Meat Inst. v. Bergland, 459 F. Supp. 1308 (D.C. Cir. 1978) (denying AMI's motion for preliminary injunction to enjoin a rule setting forth procedures for monitoring the processing of bacon and regulating the presence of nitrosamines); *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972) (holding that federal ingredient standards issued by the Secretary pursuant to Section 607(c) for sausages preempt conflicting state standards); U.S. v 1,500 Cases More or Less, Tomato Paste, 236 F.2d 208 (7th Cir. 1956) (interpreting the FDCA Section and finding that confiscated product was misbranded because it contained levels of mold above the "tolerance levels" that FDA had set for mold pursuant to FDCA Section 341(a)(3), which is the equivalent to FMIA section 602(3) and (4), both inapplicable here); W. B. Wood Mfg. Co. v. United States, 286 F. 84 (7th Cir. 1923) (interpreting in a confiscation libel case the FDCA "added deleterious substance" section and finding that confiscated product was misbranded because it

The Congressional power that the Meat Industry invoked in its description of FMIA is impressive; but not nearly as impressive as the meat-inspection system it purports to describe. According to the meat industry, "Congress specifically prohibits any meat from leaving an official establishment until FSIS *affirmatively* determines the meat is 'not adulterated.'"[182] If this were only true, the thousands of children and adults injured or killed in outbreaks caused by contaminated meat would be a lot happier and alive.

Just as it did in the Court of Appeals, the Meat Industry tried to sell a version of federal inspection and regulation in which each and every meat product is closely inspected and certified safe before it leaves the meat plant. Apparently hoping that the careful analysis of the current HACCP-based meat inspection process in *Kriefall* would be ignored, seeking further appellate review, the Meat Industry continued to insist that USDA, in essence, runs every federally-inpected meat processing facility in the country. This was the primary argument rejected by the *Kriefall* court, however, and probably also the reason that the meat industry's position lacked credibility. As the *Kriefall* court had explained:

> Effective January 26, 1998, for meat processors with more than 500 employees, the Food Safety and Inspection Service delegated to the meat processors themselves the responsibility of coming up with procedures, designated as a Hazard Analysis and Critical Control Point system, adapted to the processors' own circumstances, to safeguard the wholesomeness of the meat they produce. (citing and quoting 9 C.F.R. § 417.2(a)(1); Pathogen Reduction, 61 Fed. Reg. at 38,869.)

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contained an unapproved food coloring); *American Nw. Selecta, Inc. v. Munoz*, 106 F. Supp. 2d 223 (D. Puerto Rico 2000) (presenting a preemption case involving regulation in conflict with FMIA labeling standard involving what information must appear on federal certificate of inspection); Cook Family Foods, Ltd. v. Voss, 781 F. Supp. 1458 (C.D. Cal. 1991) (calculating the effect of added water in determining the labeled-weight of hams sold in California); Kircos v. Holiday Food Ctr., Inc., 477 N.W.2d 130 (Mich. Ct. App. 1991) (providing a non-controlling opinion of the Michigan Court of Appeals involving trichinosis in pork); Kraft Foods N. Am., Inc. v. Rockland County Dep't of Weights and Measures, No. 01 Civ. 6980, 2003 WL 554796 (S.D.N.Y. 2003) (finding in a labeling and misbranding case that the FMIA regulations governing food label net-weight statements preempted conflicting county regulations); Gorton v. American Cyanamid Co., 522 N.W.2d 746 (Wis. 1995) (addressing the issue of FIFRA preemption involving herbicide labeling)).

182. *See* Petition for Review, at 7, *Kriefall*, 671 N.W.2d 849 (citing 21 U.S.C. § 602) (emphasis added).

> As further summarized by the Department in a June 2000 report issued by its Office of Inspector General, the new program was designed to "reverse[]" the arrangement under which "the production of meat and poultry products was monitored at every stage by Government employees" to a system that "allowed a plant to monitor itself." U.S.D.A. Rep. No. 24001-3-At, at 1 (2000). Thus, the new plan, as phrased by the report, "gave [meat] industry, not Government, the primary responsibility for ensuring the safety of meat and poultry products."[183]

Yet, the Meat Industry's continued insistence that FSIS controls all aspects of its operation and guarantees that no adulterated meat leaves its facility seems in the end to be little more than self-serving rhetoric divorced from reality. If the Meat Industry's position was true, there would be no need for product-recalls because no adulterated meat would ever leave a meat-processing facility and enter the stream of commerce.

The Meat Industry twisted language and logic in a failed attempt to explain how *E. coli* O157:H7, which is indisputably an adulterant, is nonetheless *not* an adulterant if it sits only on the surface of meat that happens to be intact at the time it leaves the processing plant. Put another way, the Meat Industry asked us to accept the notion that the presence of an adulterant on meat does not make the meat "adulterated." To do so, it repeatedly invoked word plays like "the *circumstances*" under which raw meat is adulterated, and the "*quantity* of the poisonous" substance required to "'*ordinarily*' render the product injurious."[184] But this word play ignores just how limited the *Kriefall* decision really was. Without questioning the USDA's authority to interpret or enforce FMIA, the court simply ruled that USDA "has only limited authority to affect the congressional definition of 'adulterant,' *other than in the area of labeling*."[185] As the Supreme Court recently pointed out in *Bates v. Dow Agrosciences*, a statute that "preempts competing state labeling standards . . . does not, however, preempt any state rules that are fully consistent with federal requirements," including particularly state tort claims premised on a claim of misbranding.[186]

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183. *Kriefall*, 665 N.W.2d at 430.

184. *See* Petition for Review, at 9 & 11, *Kriefall*, 671 N.W.2d 849 (emphasis added).

185. *Kriefall*, 665 N.W.2d at 425 (emphasis added).

186. *Bates*, 544 U.S. at __, 125 S.Ct. at 1803.

The *Kriefall* decision therefore gets it right by recognizing a crucial distinction between the preemptive effect of the agency's authority to establish uniform labels, and its authority to declare (or not declare) a pathogen as an adulterant. This made unnecessary any analysis of the spin that the Meat Industry was putting on the Non-Intact Meat Policy Statement.[187]

2. *E. coli* O157:H7 as Natural, and Inevitable, to Meat

In its castigation of the Court of Appeal's decision, the Meat Industry assumed that *E. coli* O157:H7 is not an "added substance" under FMIA.[188] But it is. Unlike the fish-bones and oyster shells that were deleterious, but not added, pathogens can be readily distinguished. Cattle become infected with *E. coli* O157:H7, and it can then spread throughout a herd, multiplying and propagating, and infecting other cattle.[189] As infected cattle excrete feces, the *E. coli* O157:H7 contaminates the cattle's hides.[190] The *E. coli* O157:H7 contaminating the hides, and in the feces and ingesta, then cross-contaminate the carcasses of other animals during the production-process.[191] There is, as a result, nothing "natural" about the presence of *E. coli* O157:H7 in meat; it is both an adulterant and a deadly "added substance."

Ignoring the foregoing, the Meat Industry still continued to argue that "*E. coli* is a *natural inhabitant* in the intestines of animals . . . [and] cannot always be avoided."[192] But FSIS has always disagreed with this argument and excuse, explaining that:

> Several commentators, including [meat] industry groups . . . were opposed to the concept that beef that test positive for *E. coli* O157:H7 be considered adulterated because the organism may

187. *See* Non-Intact Meat Policy Statement, 64 Fed. Reg. 2803.

188. *See* 21 U.S.C. § 601(m)(1) (2000). The "ordinarily injurious to health"—a less strict standard that allows for tolerance levels—only applies if the poisonous or deleterious substance "is *not* an added substance." *Id.* (emphasis added).

189. *E. coli* O157:H7 Contamination of Beef Products, 67 Fed. Reg. at 62,327.

190. *Id. See also* HACCP Final Rule, 61 Fed. Reg. at 38,837 (stating that "fecal contamination of carcasses is the primary avenue for contamination").

191. HACCP Final Rule, 61 Fed. Reg. at 38,837 ("Pathogens may reside in fecal material, ingesta, both within the gastrointestinal tract and on the exterior surfaces of the animals going to slaughter.").

192. *See* Petition for Review, at 10, *Kriefall*, 671 N.W.2d 849 (emphasis in original).

> be inherent in raw meat and poultry when produced under current technology.
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> Under FMIA, a product is "adulterated" if "it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health . . . ." (21 U.S.C. 601(m)(1)) Because beef products contaminated with [*E. coli*] O157:H7 are often cooked in a manner that may not prevent illness, this pathogen is a substance that renders "injurious to health" even products that many consumers consider to be properly cooked.[193]

Therefore, the *Kriefall* decision was right to reject the Meat Industry's argument in finding that the "goal of the Food Safety and Inspection Service and the Hazard Analysis and Critical Control Point plans it implements is to 'prevent' fecal contamination and *E. coli* contamination—what the agency called 'zero tolerance' for fecal contamination and the concomitant reduction of the *E. coli* bacterium to an 'undetectable level.'"[194]

3. Consumer Responsibility vs. Meat Industry Responsibility: Just Cook It

The *Kriefall* decision is also buttressed by the FSIS's prior rejection of the meat industry's argument, repeated by Excel in its Petition, that it is the consumer's responsibility to make the meat it purchases safe to eat—a sort of caveat esor, or eater beware, policy.[195] FSIS notes:

> Several industry commentators stated that consumers should assume more responsibility for their safety and expressed the need for consumer awareness programs regarding the importance of cooking beef products thoroughly.

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193. Recent Developments Regarding Beef Products Contaminated with *E. coli* O157:H7, 65 Fed. Reg. 6881, 6884 (Feb. 11, 2000).

194. *Kriefall*, 665 N.W.2d at 435 (citing 61 Fed. Reg. at 38,850; 67 Fed. Reg. at 62,329).

195. *See* Petition for Review, at vii, *Kriefall*, 671 N.W.2d 849 (stating that "the dangers are *easily avoided* in intact meat through proper handling and cooking") (emphasis in original).

> Industry can reduce *or eliminate* risk associated with [*E. coli*] O157:H7 through various controls and interventions . . . that can be incorporated into HACCP systems. Because industry has the means to reduce or *eliminate* the hazard, consumers should not be expected to assume all the responsibility for preventing foodborne illness associated with [*E. coli*] O157:H7.[196]

The Meat Industry's caveat esor policy was thus rightly rejected by the Court of Appeals. The Meat Industry was predictably outraged at the court's elevation of public interest in the safety of the meat supply over purely economic concerns. Indeed, in its amicus brief filed with the United States Supreme Court, the Meat Industry claimed that the court's focus is "on people's health and safety . . . blinded [it] to the other statutory objectives [of FMIA]—namely, promoting the national market for wholesome meat and protecting the meat industry from losses."[197] A better "us versus them" statement by the Meat Industry would be hard to find, the crux of which plainly is: more death and illness is the cost of doing business, and the cost should be borne by consumers, not the Meat Industry.

Finally, it is worth emphasizing that, despite its insistence on consumer responsibility, and its preference for consumer education above all, the Meat Industry has impeded more than helped providing accurate and complete information to the public. For example, when in the wake of the Jack in the Box outbreak USDA wanted to put warning labels that included the temperature to which ground beef should be cooked to, the Meat Industry sued to stop it.[198] And while the Meat Industry and USDA has stepped-up consumer education efforts, the information continues to be either inadequate or inaccurate. For example, consumers are told to use a meat thermometer, but the bi-metallic coil thermometer indicated

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196. 65 Fed. Reg. 6881, 6884 (emphasis added).

197. Brief of Amici Curiae, at 20, *Kriefall*, 541 U.S. 956 (2004) (citing 21 U.S.C. § 602) [hereinafter Brief of Amici].

198. NESTLE, *supra* note 21, at 77 (noting that the Meat Industry "did not want package labels to suggest that anything might be inherently wrong with their product."). *See* American Pub. Health Ass'n v. Butz, 511 F.2d 331 (D.C. Cir. 1974) (in a divided decision, ruling that the USDA need not require warning labels with cooking instruction on meat and poultry). For a helpful discussion of this decision, and the USDA's support for the Meat Industry's position against warning labels, see NESTLE, *supra* note 21, at 65-67. Of course, in the wake of the Jack in the Box outbreak, the Meat Industry changes its position. *Id.* at 76-78. And now the Meat Industry uses the existence of these labels to buttress its argument that it is the consumer's sole duty make meat safe to it.

on the USDA warning-label is ineffective and inaccurate, and using it "can jeopardize public health, particularly the health of the young, elderly, and immune-compromised portion of the population."[199] And recent research continues to show that, while consumers have a high level of concern about food safety, they do not have a correspondingly high awareness of the practices required for safe food production.[200] Moreover, "data suggest that many consumers are unaware that food safety problems are likely to occur in their homes, believing that the responsibility for food safety lies instead with food manufacturers and restaurants."[201]

IV. AGAINST PREEMPTION: ONE SIZE DOES NOT FIT ALL

> I must confess that my trust is in the jury and the tort law whose operations I can see, rather than in an administrative body, whose fairness and comprehensiveness I can only pray for. Preemption by regulation is a doctrine that makes me nervous in a world of rapidly developing technological dangers and wonders.[202]

Foodborne illness remains an overwhelming problem in the United States. The best and most recent estimate concluded that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.[203] Compared to other regulated products, even those subject to mandatory recall authority, food products cause more deaths each

199. O. Peter Snyder, *Food Temperature Variations Along The Stem Of The Bimetallic-Coil Thermometer*, 19 DAIRY FOOD ENVIRON. SANITATION (no. 7) 477, 481, 483 (1999) ("The data show that it was difficult to assess when the hamburger was done without the use of a thermocouple.").

200. Elizabeth C. Redmond & Christopher J. Griffith, *Consumer Food Handling in the Home: A Review of Food Safety Studies*, 66 J. FOOD PROTECTION (No. 1) 130, 136 (2003) (noting, for example, that responses to surveys "have shown that [forty percent] of consumers did not know or were not consciously aware that they were using unsafe practices").

201. *Id.*

202. Jack B. Weinstein, *Symposium: The Restatement of Torts and the Courts*, 54 VAND. L. REV. 1439, 1442 (Apr. 2001). Mr. Weinstein is Senior Judge, United States District Court, Eastern District of New York. *Id.* at 1439.

203. Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECT. DIS. (No. 5) 607, 614 (1999). Also finding that unknown agents account for eighty-one percent of foodborne illnesses and hospitalizations, and sixty-four percent of deaths. *Id.* at 616.

year than other regulated products.[204] "In fact, contaminated food products caused more deaths each year than the combined totals of all 15,000 products regulated by the [United States] Consumer Product Safety Commission."[205]

"Despite regulatory efforts to improve the safety of the U.S. food supply, foodborne *E. coli* O157:H7 outbreaks remain common. Ground beef remains the most frequently identified vehicle."[206] Thus, notwithstanding the Meat Industry's claim that allowing state tort claims premised on FMIA adulteration standards will do "violence to an effective and proven statutory and administrative scheme,"[207] there is no evidence the current scheme is either effective or proven. In fact, there is much evidence to the contrary.[208] Moreover, there is both evidence and cogent arguments demonstrating that lawsuits can (and should) provide important and needed feedback to the Meat Industry about the safety of its products.[209] Such lawsuits also create needed economic incentives to

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204. Jean C. Buzby et al., Economic Research Service/USDA, *Product Liability and Microbial Foodborne Illness*, at 1 (AER-799 2001), *available at* http://www.ers.usda.gov/publications/aer799/aer799b.pdf ("Pathogen contaminated foods . . . represent an important cause of unintentional injury and death.").

205. *Id.*

206. Rangel et al., *supra* note 34, at 606.

207. Brief of Amici, *supra* note 197, at 20. *See also* Petition for a Writ of Certiorari, at 3, *Excel Corp. v. Estate of Kriefall*, 541 U.S. 956 (2004) [hereinafter Petition for Writ] (stating "the decision below significantly undermines an important regulatory system"). That USDA has, in the time since the *Kriefall* decision upheld, continued on with its regulatory activities without any apparent disruption or change, not even abandoning its policies regarding *E. coli* O157:H7 on intact cuts of meat, further reveals the in terrorem nature of the Meat Industry's arguments.

208. General Accounting Office, Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. SENATE, *MEAT AND POULTRY: Better USDA Oversight and Enforcement of Safety Rules Need to Reduce Risk of Foodborne Illnesses*, GAO-02-902, at 4, *available at* http://www.gao.gov/new.items/d02902.pdf. "FSIS is not ensuring that all plants' HACCP plans meet regulatory requirements and, as a result, consumers may be unnecessarily exposed to unsafe foods that can cause foodborne illness."

209. Buzby et al., *supra* note 204, at 9 (suggesting "economic theory suggests that foodborne illness litigation provides signals to firms to invest more in food safety, ultimately resulting in a lower incidence of foodborne illness and an increase in general social welfare."). *But see* Lassiter, *supra* note 66, at 417 ("civil action through consumer lawsuits seeking monetary damages have failed to shift the cost-benefit analysis for the [Meat Industry] enough to alter the status quo."). Professor Lassiter's conclusion that foodborne illness litigation cannot "provide sufficient incentive for meat producers to provide a safe meat supply to the public," is more

invest in improved food safety technology and innovation.[210] That food safety innovation is desirable should arguably go without saying: "Widespread diffusion of food safety innovation not only increases choice and economic efficiency, it also saves lives and improves health . . . . Innovation and the adoption and diffusion of food safety improvements will help combat foodborne illness and improve the quality of life for all Americans."[211] But innovation is not occurring in sufficient measure to sustain further food safety improvement given the persistence of *E. coli* O157:H7 and other deadly pathogens in our food supply.

One commentator calls the resistance to investment in food safety innovation "the paradox of an industry committed to safety, but also not wanting to spend the money for safety improvements because it is perceived as unprofitable."[212] This perception exists even though the USDA Economic Research Service determined that the annual cost to plants of HACCP compliance has increased no

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asserted than proven. *Accord* Roots, *supra* note 66, at 2431-32 (criticizing Professor Lassiter's reliance on cited authorities that do not in fact support her position, and describing as absurd her contention that the multimillion dollar settlements that were obtained in the Jack in the Box outbreak cases had no effect upon corporate conduct). A complete rebuttal of Professor Lassiter's flawed analysis, including its failure to take into account the application of strict liability to defective food cases, and to distinguish between outbreak versus sporadic cases in the proof of causation, must await another article.

210. *See* Buzby et al., *supra* note 204, at 9; *Bates*, 544 U.S. at __, 125 S. Ct. at 1802 (stating that "the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from the use of their product so as to forestall such actions through product improvements").

211. Elise Golan et al., ERS/USDA, *Food Safety Innovation in the United States: Economic Theory & Empirical Evidence From the Meat Industry*, at 2 (AER-831 Apr. 2004) (finding that while foodborne disease outbreaks spur the demand for safety and innovation, overall the core drivers of innovation are relatively weak for food safety).

212. Fortin, *supra* note 66, at 574 (proposing the enactment of a Citizen's Food Protection Act that would, inter alia, create judicial review of administrative action and a private right of action for even those not injured by unwholesome food to sue to enjoin "conduct that has, or is likely to have, the effect of adulterating or impairing the cleanliness, safety or wholesomeness or food"). *Id.* at 591. Without taking a position on the need or likely efficacy of the Act in improving food safety, I strongly agree with Mr. Fortin that "access to the courts can provide the best solution to the risk of agency capture, inadequate government resources, and the dilemma of the insider perspective." *Id.* at 587.

more than one-third of one cent per pound, and increased the cost of meat and poultry products less than one-percent.[213]

Another reason for the resistance to voluntary investment in food safety innovation is the absence of an obvious profit-motive. Consumers cannot detect food safety, making it difficult for a manufacturer to market safety as a product attribute, or more importantly, for which to charge a premium.[214] As one economic analysis performed by USDA found:

> Consumers do not have complete information about the safety of products they buy because producers have no direct incentive to provide this information. Since it is not clear whether consumers can distinguish different safety levels in food products, firms may not wish to incur the cost of providing more than the minimum required level of safety in the food products they market.[215]

Consequently, except for the compelled investments required to achieve regulatory compliance, the desire to avoid the unwanted costs associated with the manufacture and sale of an unsafe product, including liability for product-related injury, is the only other remaining compelling reasonincentive for voluntary investement in food safety innovation.[216]

The resistance (or disinclination) to voluntarily invest in food safety is highest for commodity-like products such as ground breef

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213. Michael Ollinger et al., USDA-ERS, *Meat and Poultry Plants' Food Safety Investments: Survey Findings*, Summary, at iii (2004), *available at* http://www.ers.usda.gov/publications/tb1911/tb1911.pdf.

214. *Id.* at 3; Golan, *supra* note 211, at 6 (noting for example that consumers cannot tell by looking at it whether ground beef contains *E. coli* O157:H7). *See also* Nigol Manoukian, *The Federal Government's Inspection and Labeling of Meat and Poultry Products: Is it Sufficient to Protect the Public's Health, Safety, and Welfare*, 21 W. ST. U. L. REV. 563, 563 (1994) ("A meat inspector can't see it, smell it, or feel it. Neither can a chef nor someone cooking hamburger on a backyard barbecue. Microbiological contamination, the most serious public health threat to the nation's food supply, cannot be detected by the human senses."). Of course, if the consumer is infected there is likely to be more than sufficient evidence of the defective nature of the product after the fact of purchase, which is to say, when it is too late to make a difference to the consumer's choice of the product.

215. Crutchfield et al., *supra* note 96, at 1-2.

216. *Id. See also* Buzby et al., *supra* note 204, at 8 (noting that "[t]hese are 'negative incentives' or adverse consequences for firms responsible for selling pathogen-contaminated food").

and subprimals sold for further-processing at retail.[217] Products like these are not subject to the market incentives applicable to manufactured products with detailed contract specification, those that are inspected for foreign export and those that are sold under the manufacturer's brand name.[218] As a result, if the manufacturers of such products could not be held financially responsible under product liability law, the only food safety incentive left would be the need for regulatory compliance.

Ultimately then, the argument against preemption is the argument against letting the Meat Industry shift the costs of its manufacturing mistakes to those injured as a result.[219] How much to invest to improve the safety of the manufacturing process is a cost-benefit analysis that manufacturers have nearly always faced. While the Meat Industry has tried to argue that the challenges it faces are unique, and "that a failure to apply federal preemption will subject the meat-processing industry to intractable dilemmas," [220] this argument must be rejected, just as the court in *Kriefall* did, aptly noting:

> [A]ll manufacturers confront difficult cost/benefit choices when balancing expense and methods of production on one hand, against, on the other hand, potential liability for injuries that may be caused by their products; we see no special burden on Excel or other meat processors beyond that faced by anyone who puts potentially dangerous products into the stream of commerce.[221]

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217. Ollinger et al., *supra* note 213, at 14. The tri-tips that were the subject of the Sizzler *E. coli* O157:H7 outbreak, and the resulting litigation, are an example of a subprimal.

218. *Id.*

219. It is not, however, just the injured person who must shoulder the costs associated with foodborne illness. It has been shown that some costs are shifted to parties other than the person who became ill, including health insurance companies for those insured, including the government for those on Medicare or Medicaid, health care providers and taxpayers for those not insured, and employers through sick-pay and in productivity losses. Buzby et al., *supra* note 204, at 7 (noting that "these cost-shifting mechanisms may reduce the economic incentives for ill individuals to seek compensation from those responsible for causing their illness."). The Author's experience handling foodborne illness damage claims strongly supports the theory that in any outbreak there will be a percentage of persons who decide that their injuries are not serious enough to justify the decision to proceed with a claim. This decision-making process merits empirical research.

220. *Kriefall*, 665 N.W.2d at 436 n.7.

221. *Id.*

The Meat Industry believes itself to be unique among regulated industries and thus entitled to its own rule on preemption. It is difficult to dispute that the Meat Industry is not at least unique in appearing "relentless and self-serving."[222]

It is primarily through our system of tort laws that those injured by others are compensated, and tortfeasors are forced to pay the full social costs of their activities.[223] Such liability is intended to motivate manufacturers to use their exclusive control of information about the manufacturing process to reduce the occurrence of product-related accidents.[224] In addition to the information advantage they possess over consumers, manufacturers are afforded a deliberate choice about the level of investment in production quality and control processes.[225] While regulations require certain things of all USDA-inspected establishments, including a HACCP plan, the details of such plans, including the technologies and interventions used, remain solely in the control of the meat industry. For example, no one requires the meat industry to run line-speeds as fast as they do.[226] This was a fact not lost on the *Kriefall* court, which noted:

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222. NESTLE, *supra* note 21, at 103 (commenting on a statement made by Rosemary Mucklow, the Executive Director of the National Meat Association, accusing USDA of proposing a change in its *E. coli* O157:H7 testing policy as a means by the White House of diverting attention from the scandal involving President Clinton and Monica Lewinsky). The author of this article is not surprised at Ms. Mucklow's statement having attended a USDA sponsored conference on pathogen reduction where, during a comment period, she stood at the microphone and said something to the effect, "if pathogens in meat is really such a problem, I'd like to be shown where the bodies are buried." Nancy Donley, whose child died as a result of an *E. coli* O157:H7 infection caused by adulterated ground beef, offered to show Ms. Mucklow where at least one such body was buried.

223. Weinstein, *supra* note 202, at 1439 (arguing that the compensatory and inhibitory aspects of tort law are particularly important in the area of mass torts and public nuisances).

224. 1 MADDEN & OWEN ON PRODUCTS LIABILITY, § 5.2 (3d ed. 2000). This rationale was the one most often emphasized by Chief Justice Traynor in those early cases holding in favor of strict product liability. *See, e.g.*, Escola v. Cola Cola Bottling Co., 150 P.2d 436, 440 (Cal. 1964) (Traynor, J., concurring). *See also* Roger W. Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363 (1965) (setting forth Justice Traynor's rationale in favor of the imposition of strict liability).

225. Owen, *supra* note 2, at 855.

226. Machado, *supra* note 15, at 812. "Microbes become introduced into the meat because of fast and sloppy slaughter practices. For example, an average line speed slaughters three hundred cattle per hour, or one cow every three seconds." *Id.*

> The record here demonstrates in a concrete way how the claims asserted against Excel supplement the protection afforded by the meat inspection program and what the Food Safety and Inspection System has recognized are the significant limitations of the "organoleptic examination by inspectors." Only two federal inspectors oversee a meat fabrication area in Excel's plants where several hundred workers daily cut the approximately seven-foot-long, 350 pound split carcasses into some 8,000 intact cuts of beef weighing approximately two to four or three to five pounds each. Federal inspectors do not inspect each one of these smaller cuts of beef. Moreover, the seven-foot-long carcasses arrive at the fabrication area after whizzing by the Service inspection station at a rate of one side every six seconds.[227]

Thus, plainly, the fact that meat is stamped with the words "inspected and passed" does not mean that inspection actually occurred or that it was effective.

Defects happen and unsafe meat gets through into interstate commerce, even with strict regulatory compliance.[228] No rational policy or regulation should assume the absence of defects, while also allowing preemption based on such an assumption. Doing so risks leaving those injured by real defects without a remedy. As long as one views compensatory damages as serving a cost-internalization process, no reason exists to think that damage awards contradict a federal safety regulation intended to protect the public health.[229] Preempting the rights of persons injured by unsafe meat based on the legal fiction that it was not adulterated because it was "inspected and passed" accomplishes no objective except to immunize the Meat Industry from liability for product defects. Such preemption also ignores that cases involving regulatory compliance generally involve products defective in design, or defective due to inadequate

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227. *Kriefall*, 665 N.W.2d at 435-36.

228. Michael, *supra* note 93, at 555-56 (emphasizing that in regulatory regime based on voluntary compliance, "there will be failures, even if the program is functioning perfectly. The relevant comparison is not to zero faults, but the results using any alternative regulatory technique.") As such, if too many defects are created as a result of a given regulatory technique, and the regulated entity remains liable for defect-related damages, then that entity is more likely to cooperate further to improve how well the regulations work.

229. Hills, *supra* note 76, at 35 (arguing that "compensatory damages can be explained by the state's judgment of corrective justice that, whatever the social benefits of some activity, the actor ought to restore person's injured by the activity to the position that they would have occupied but for their injuries.").

warnings.[230] A company might convincingly argue that its product information was not legally deficient because it contained all information required by the agency that approved it. The same cannot be said for a company that argues, as Excel did, that meat contaminated with a deadly pathogen cannot be treated as defective—which is to say, unsafe beyond that reasonably expected by an ordinary consumer—under state tort law solely because it came from a federally-inspected meat-processing facility.

Adulteration standards should therefore be viewed for what they are—minimal safety standards.[231] To require compensation under state law does nothing to undermine those standards. A successful product liability lawsuit does not impose a recall on a company or subject it to increased regulation or enforcement.[232] As is the case with strict product liability involving manufacturing defects, the

230. Richard C. Ausness, *The Case For a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1226 (1996) ("In recent years, manufacturers have argued that tort claims should be barred by the preemption doctrine when their products comply with applicable federal labeling and design requirements."). *See also* Schwartz, *supra* note 102, at 1128-29 (offering cogent criticism of tort "reform" proposals that would make compliance with federally-issued product safety standards a complete defense to a product liability claim, and arguing that such standards should continue to be treated as minimum, not maximum, standards of care). *See also* Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as The Government Standards Defense*, 37 WM. & MARY L. REV. 903 (1996) (arguing that "*Cipollone* makes the most sense if interpreted as announcing a federal common law rule accepting the government standards defense rather than as a true preemption defense available in tort actions.").

231. Weinstein, *supra* note 202, at 1442 (claiming "administratively-determined product safety standards . . . should merely provide minimum standards, not supplant tort law."). *See also* Lisa Lovett, *Food for Thought: Consistent Protocol Could Strengthen Food Supply Security Measures*, 10 TEX. WESLEYAN L. REV. 465, 471 (2004) (making the interesting, albeit probably over-optimistic, argument regarding the number of pits allowed in a can of "pitted" cherries, that "in practice, USDA standards are not as rigorous as what cautious fruit based manufacturers would require in order to maintain their customer base, and although deemed 'pitted' by the USDA, these manufacturers would likely further screen these cherries before processing them."). Whether Ms. Lovett is correct in her prediction about the cherry-processor, however, it seems safe to assume that no extra care or further processing would be used if it was certain that the USDA standards preempted state tort claims and there was no risk of being held liable for injuries caused by a pit in "pitted" cherry.

232. The author is unaware of any food recall ever prompted by the filing of a lawsuit. Lawsuits follow recalls and foodborne illness outbreaks; they do not precede them.

defect in the product represents a departure from its specification, and it is this departure for which the manufacturer is held strictly liable.[233] By continuing to allow the Meat Industry to be held liable for the injuries caused by meat made unsafe because of a processing defect, the Agency is doing what courts and modern tort law have long done—making a tortfeasor pay for the damages it caused as a result of its failure to use the care necessary to avoid creating the defect that caused the injury.

Given the chaos involved with preemption analysis, and the Agency's proclivity for ambiguous policy statements and sudden policy-changes in the face of public outrage or political pressure, regulatory preemption of state tort laws is likely to be no more uniform than what exists at present. Consequently, the goal of uniformity is not in conflict with the purpose of protecting the public health, but a policy of implied preemption is. "Court decisions on preemption are inconsistent and appear to have little predictive value."[234]

An explanation for such inconsistency may rest with the fact that too often regulatory silence will be ambiguous and even close scrutiny of the regulatory history may not reveal a clear answer. A recent General Accounting Office study of several health and safety agencies found that the basis for regulatory decisions frequently was unclear. Because agencies do not intend or expect their regulations to be used to define tort liability, it is unsurprising when these regulations are not drafted in ways that assist the court.[235] Agencies should expect though, especially USDA in light of the decision in

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233. Strict liability exists in some form in all fifty states. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY 1 (1998). Not all states, however, call it strict liability. For example, in Michigan, such liability is still treated as a form of implied warranty. *See, e.g., Vincent v. Allen Bradley Co.*, 291 N.W.2d 1 (Mich. 1980) (holding that a breach of implied warranty is established on proof of injury caused by a defect in the product, attributable to the manufacturer, that made the product not reasonably fit for its intended use).

234. Ausness, *supra* note 230, at 1234 ("Thus, manufacturers who believe that federal safety standards preempt tort liability must engage in lengthy and expensive litigation in order to obtain an authoritative decision from the courts on the issue. This failing greatly reduces the value of the preemption doctrine as a 'safe harbor' for manufacturers whose products satisfy federal regulatory standards.").

235. Schwartz, *supra* note 102, at 1132 (footnotes omitted). While the use of regulations to seek preemption of state tort claims may have been unsurprising at the time of Professor Schwarz's article, it would be surprising for an agency to be unaware of this issue now.

Kriefall, that the meat industry intends to use its rules and policies as a preemption defense.

Agencies charged with protecting the public should not impliedly preempt the rights of those injured by unsafe meat to seek compensation under state law.[236] If we must accept that an agency has the power to preempt, it should, at a minimum, accept the same limits as those that apply to Congress, the source of its authority. This means USDA, like Congress or any other agency, must be accountable to the public, rather than deferential to the Meat Industry it regulates.[237] It also means that the decision process must be transparent, and the decision made that it makes be clear and consistent.[238] To-date, the *E. coli* O157:H7 policy decisions made by USDA have been none of these things.

In *Kriefall*, for example, the court might have avoided a direct ruling on the scope of Agency authority by simply finding that the Agency's policy statement was not sufficiently clear to preempt state law that might be to the contrary.[239] The Agency's statements concerning intact meat and *E. coli* O157:H7 had hardly been consistent.[240] By its own admission, the policy statement was part of a continuing reassessment that was subject to subsequent change. Indeed, since the policy statement first issued, and the appeals in *Kriefall* had come to an end, the Agency has continued to do a substantial amount of work in the area of intact versus non-intact meat.[241] Given this changing landscape, one might reasonably ask

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236. *See* Ausness, *supra* note 230, at 1237-38 (discussing failures of preemption as method of promoting product safety).

237. *See* Herrman, *supra* note 19, at 1197 ("A necessary premise to our system of federalism is the notion that administrative rulemaking must somehow be accountable to the American people in order to preserve a constitutionally mandated balance in the area of preemption.").

238. *See* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559 (1997) (criticizing what she calls the Supreme Court's "schizophrenic approach" to preemption analysis, and arguing that courts should require an unmistakably clear intent from Congress before dismissing state tort claims as preempted).

239. The court seemed to recognize this when it noted that "even the Department's own regulations defining the word 'adulterated,' *as opposed to its less formal pronouncements*, make no distinction between contaminated intact meat and contaminated non-intact meat." *Kriefall*, 665 N.W.2d at 429 (emphasis added).

240. *See* discussion *supra* notes 82 & 83 and accompanying text.

241. *See, e.g.*, FSIS Notice 32-05, Verification of Establishment's Reassessment of HACCP Plans to Address Mechanically Tenderized Beef Products (June 1, 2005) (stating that the reassessment was necessary because of "three recent outbreaks of

on what basis a state tort claim should be dismissed with prejudice if, at some later point in time, the regulatory position that formed the basis of the dismissal is reversed. Accordingly, it makes little sense to premise a preemption decision on policy that is in anyway unclear evolving, or otherwise subject to possible future change.

Finally, if the Agency believes that its effective regulation requires the preemption of state tort claims premised on FMIA, then it should make its case public and go about the task of issuing a final rule on the subject. Early statements by the Agency indicated that the HACCP Final Rule was not intended to have any preemptive effect. The Agency stated that an "establishment's liability to civil lawsuits should not be adversely affected by this rule precisely because it is an establishment's process, not individual lots of product, that is being assessed, for inspection purposes, on the basis of this testing."[242] Since then, however, the Agency has been silent on the issue of preemption, despite the high profile efforts of the Meat Industry to use its *E. coli* O157:H7 policy, among other things, to obtain immunity from civil lawsuits. "The door is wide open for federal agencies to exert far greater influence on the preemption question."[243] The Agency should therefore speak up, and do so clearly, on this issue. Clarity may not stop the Meat Industry's efforts to immunize itself from liability for the harm caused by unsafe meat, but it will at least make the effort less likely to succeed.

V. CONCLUSION

In enacting FMIA, Congress intended "to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State or other Government agencies to accomplish this objective."[244] The goal of

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disease from [*E. coli* O157:H7] associated with the consumption of mechanically tenderized beef.") One of the outbreaks mentioned was the Sizzler outbreak.

242. HACCP Final Rule, 61 Fed. Reg. at 38,806, 38,854. The *Kriefall* court did not give this statement any weight, and it was not the basis of its decision. The court noted, however, that "it is far from settled that an agency's view of the preemptive effect of a statute is given *any* deference." *Kriefall*, 665 N.W.2d at 437 (emphasis in original).

243. Scott A. Smith & Duana Grage, *Federal Preemption of State Products Liability Actions*, 27 WM. MITCHELL L. REV. 391, 416 (2000). Smith and Grage state that "the preemption defense is almost certain to remain highly politicized." *Id.* at 415.

244. 21 U.S.C. § 661 (2000).

the Agency should be to enact regulations that result in the removal of pathogens from the meat supply, farm to table. The fact that this is a difficult goal to fully achieve is no reason to change it. Agency policy making regarding the issue of *E. coli* O157:H7 has been a case-study in reactionary rulemaking and agency capture. The *Kriefall* decision makes plain that the Meat Industry intends to use preemption to try to create de facto uniform standards that will endanger the public while leaving people injured by unsafe meat without a remedy.

To avoid such a result, the Agency should provide a clear directive on the subject of preemption, while also changing course on its *E. coli* O157:H7 policy. Only a zero-tolerance policy for *E. coli* O157:H7 applied to all meat will achieve Congress' objective. The court in *Kriefall* found that such a zero-tolerance policy currently exists, but the USDA's conflicting and ambiguous statements on the subject call the existence of such policy into serious question. Until we fully understand this decidedly deadly pathogen, there is simply no room for error in protecting the public. We should therefore commit ourselves and the resources of our government to ensuring that *E. coli* O157:H7 never contaminates meat of any kind, any quantity, and in any way.